MODELING INDIVIDUAL NOISE-INDUCED HEARING LOSS RISK WITH PROXY METRICS OF EXTERNAL-EAR AMPLIFICATION

by

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This dissertation is dedicated to my loving family.

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by

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April 2019

MODELING INDIVIDUAL NOISE-INDUCED HEARING LOSS RISK

WITH PROXY METRICS OF EXTERNAL-EAR AMPLIFICATION

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Noise-induced hearing loss (NIHL) can be incurred from occupational or recreational noise exposure. Regardless, NIHL is a preventable form of hearing loss; with accurate knowledge of risk and protective strategies, it can be avoided in almost all cases. Nonetheless, it presents with astounding global incidence, prevalence, and financial toll; there is an immediate need to redesign and strengthen hearing conservation efforts. Two primary factors categorize high-risk NIHL populations: 1) over-exposure to dangerous noise, and 2) individual vulnerability to auditory injury from dangerous noise. At present, established NIHL-risk criteria exist to identify noise over-exposure, accomplished by measuring the sound-level and duration of the exposure; however, there is currently no way to identify individuals who are inherently more vulnerable to auditory injury, as variable vulnerability has never been sufficiently explained. There is a strong possibility that the contribution of external-ear amplification could influence individual vulnerability in NIHL-risk, as amplification is likely to vary across individuals due to ear size and shape.

This research tested the hypothesis that 1) participant's NIHL-risk estimation will considerably differ after accounting for individual external-ear amplification, and 2) external-ear amplification can be estimated by non-invasive and less-technical proxy metrics (e.g., pinna size, earcanal size, body height).

158 participants (age 4-8, 13-17, and 18+ years) completed a demographic questionnaire, otoscopy, tympanometry, pinna measurement, and external-ear amplification measurements during noise stimuli. Noise stimuli included a 58 dB-A pink-noise presented in the free-field and a 53 dB-A pink-noise presented via insert-earphones. Two external-ear measurements (one for each stimulus, respectively) were obtained: 1) amplification derived from combined external-ear structures (i.e., pinna, concha, earcanal), and 2) amplification derived solely from the earcanal structure. External-ear amplification measurement #1 was obtained by placing a probe-microphone near the eardrum, and calculating the pink-noise sound-level difference between the microphone inside the ear and another microphone which measured the sound-level outside the ear; external-ear amplification measurement #2 was obtained by comparing the sound-level recorded by the microphone inside the participant's ear to the sound-level observed inside a 2.0 cc reference coupler. Individual variability in noise-dose and subsequent NIHL-risk was estimated in hypothetical scenarios after adjusting for the participant's external-ear amplification added to the sound-level of the exposure. Correlations between external-ear amplification and hypothesized proxy metrics were evaluated.

Amplification derived from combined external-ear structures (i.e., pinna, concha, and earcanal) was highly variable (5-19 dB-A), confirming large variability in estimated individual NIHL-risk for free-field exposures; participants with highest amplification were estimated to accrue up to 7x higher in-ear noise-dose than participants with lowest amplification. This type of amplification can be reliably estimated using the proxy metric of pinna height ($p < .05$). Further, external-ear amplification derived solely from the earcanal structure was highly variable (8-19 dB-A), confirming considerable variation in in-ear NIHL-risk estimation in an ear-level exposures (e.g., earbud music-listening) (safe-listening durations ranging from 6-28 hours). This type of amplification can be reliably estimated using the proxy metrics body height or earcanal size ($p < .05$). Proxy metric accuracy was confirmed in a separate dataset**.**

External-ear amplification was observed to be highly variable in this study; it is likely that this degree of variability is a source of individual vulnerability to NIHL, given that more noise means more risk. The data from this thesis identify potential non-technical proxy metrics that could reliably estimate external-ear amplification. Taken together, these results make it possible to imagine the inclusion of external-ear amplification as a risk-factor for identification of individuals at risk for NIHL.

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CHAPTER 1

INTRODUCTION

The leading causes of hearing loss are 1) aging, and 2) a history of acute and/or chronic noise overexposure (Rabinowitz. 2000). Both aging and noise-exposure result in the degeneration of cochlear outer hair cells (OHCs), which are responsible for amplifying sound in the inner ear. While prevention of age-related hearing loss is not yet possible, noise-induced hearing loss (NIHL) is 100% preventable with proper knowledge of risk and corresponding use of protective strategies. In spite of this, NIHL is the 1st/2nd most common occupational disease, and a review of 2011-2012 NHANES data showed audiometric notches suggestive of NIHL in an estimated 24% (40 million adults) of the general U.S. population (Carroll et al., 2017). Within noise-exposed populations of workers, Masterson et al. (2016) estimate that 25% of U.S. workers (across all industries) have significant NIHL, in spite of the Occupational Safety and Health Administration (OSHA) federal regulations set forth to protect against it (29 CFR 1910.95 OSHA, 1983). The U.S. federal noise regulations are set such that 1 out of 4 workers is expected to develop significant hearing loss after a 40 year career in noisy work conditions; this has been the topic of significant debate and discussion (see NIOSH, 1998, for example). The data from Masterson et al. (2016) clearly suggest that mandatory use of hearing protection devices in the workplace, and requirements for education and annual audiometric testing, are inadequate in preventing hearing loss in individuals exposed to occupational noise (Groenewold, Masterson, Themann, & Davis, 2014).

NIHL-risk is mathematically estimated from a balance of sound-level of the exposure (dB-A) and duration of the exposure (time), in order to quantify risk as a “noise-dose”. The permissible exposure limit (PEL) in the U.S. is set at 90 dB-A for 8 hours (i.e., “100% noise-dose”). In order to calculate a noise-dose from an exposure with sound-levels different than 90 dB-A, and durations different than 8 hours, the following equation is given: Dose = 100(C/T), where C = hours the worker is in the exposure, and T = reference hours of the exposure; T is derived as the number of hours the measured sound-level would be permissible until it yielded 100% dose. If a worker’s noise-dose exceeds 100%, it signifies that their time-weighted average (TWA) (weighted sound-level and duration) exceeded the permissible 90 dB-A level for an 8 hr duration; see examples in Table 1. In the U.S., according to OSHA federal regulation 29 CFR 1910.95, NIHL-risk is assumed to increase at a 5-dB exchange rate: this means that with every 5-dB sound-level increase or decrease, noise-dose doubles or halves, respectively. Similarly, with every doubling or halving of exposure duration, noise-dose doubles or halves, respectively.

Table 1.

This table demonstrates the relationship between measured sound-level of an exposure, duration of the exposure, and the subsequent calculation of noise-dose for the exposure, as is federally regulated by OSHA in the U.S. OSHA regulations state that workers exceeding 100% noise-dose permissible exposure limit are federally required to wear hearing protection devices during their workday. Notably, the PEL for workers who have previously experienced a standard-threshold shift is lowered to 50% noise-dose.

OSHA Noise-Dose and NIHL-Risk Examples

Measured sound-level (L)	Duration of exposure (C)	Dose	Time-weighted Average Level for 8-hr
90 dB-A	8	100%	90 dB-A
95 dB-A	8	200%	95 dB-A
95 dB-A	4	100%	90 dB-A
90 dB-A	4	50%	85 dB-A

Although the U.S. PEL is set to 90 dB-A for 8 hours with a 5-dB exchange rate, there is no universal agreement on the sound-level at which NIHL-risk begins, nor on the rate at which NIHL risk increases (see Dobie & Clark, 2014; Dobie & Clark, 2015; Morata et al., 2015). In fact, the PEL is set lower than 90 dB-A in most developed countries (PELs range from 80-90 dB-A), with a smaller exchange rate (3 dB-A, with a few exceptions of 5 dB-A) (see Suter, 2007). The scientific community lacks substantial data to agree on the sound-level at which NIHL-risk begins and at what rate it increases, in addition to disagreements about which audiometric frequencies to include in the quantification of hearing-loss, how much hearing-loss constitutes a handicap, and how to define the rate at which the handicap grows. However, there is widespread agreement that the higher the sound-level of a noise-exposure, the higher the risk of NIHL; in short, more noise means more risk.

NIHL can be induced not only by exposure to work-related noise, but also by exposures endured at home or at play, such as during the use of power tools or machinery, attending bars with loud music, concerts, loud sporting events such as NASCAR racing, hunting, etc. Although the hearing health of those who are employed to work at these recreational pastimes is monitored under OSHA protections, recreational noise-exposure for attendees at such pastimes is not regulated in the U.S. The World Health Organization (WHO) estimates that 1.1 billion young people worldwide may be at risk for NIHL due to unsafe music listening habits (2015) - in fact, attending just a single music event can surpass regulatory exposure limits for a single workday (Neitzel & Fligor, 2017). Recently, Grinn et al. (2017) documented acute, recreational music exposures at bars with live music, concerts, and music festivals, with OSHA noise-doses averaging 98% (range 4–318%); this mean and range excludes 2 outlier participants who attended 3-day music festivals and averaged 1,086% noise-dose (range 941–1,231%). Further, Henderson et al. (2010) concluded that 17% of teenagers (12-19 years) are estimated to exhibit NIHL in one or both ears (defined as >15 dB-HL pure-tone-average decrease between 3-6 kHz). The Center for Disease Control is recommending that all possible steps be taken to prevent NIHL incurred by dangerously loud recreational activities (2017). The field is now tasked with generating innovative approaches to reducing the incidence and prevalence of NIHL, beyond our tired (and evidently, ineffective) message to the public: “Noise is bad - wear earplugs”.

CHAPTER 2

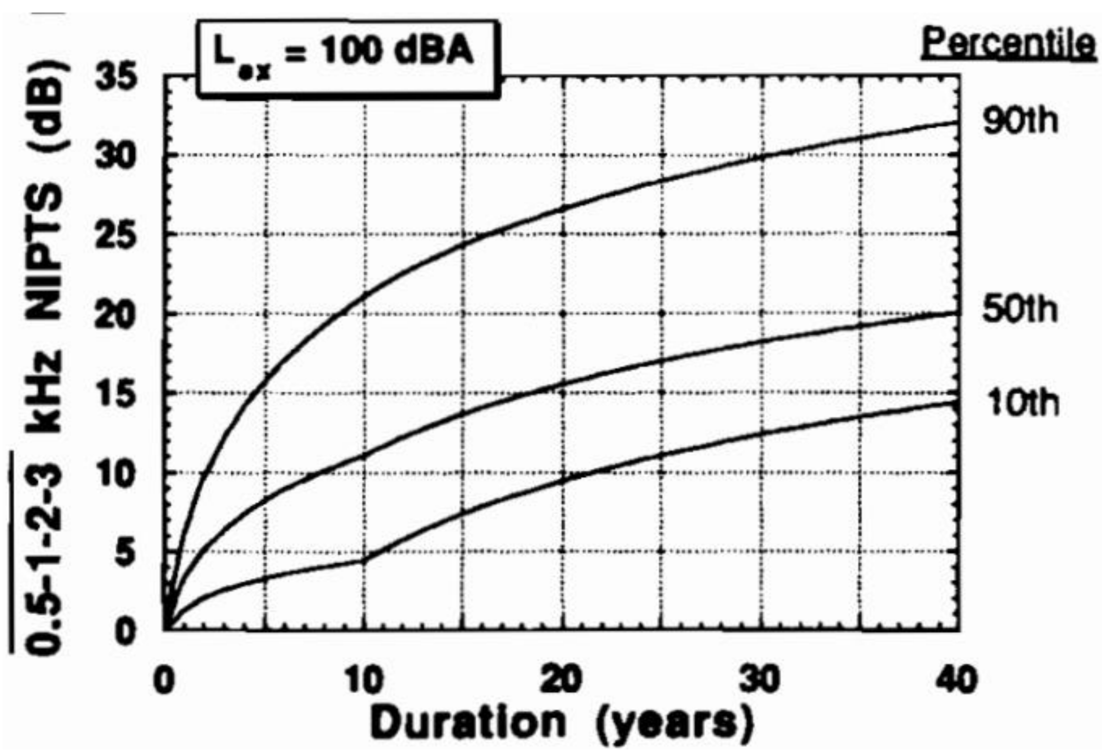
REVIEW OF THE LITERATURE

2.1 Variable NIHL Susceptibility

There is extensive debate regarding the point at which risk of developing NIHL "begins"; however, it is universally accepted that individual NIHL-risk increases as either the sound-level and/or the duration of noise-exposure increases. Despite the well-known dependence of risk on sound-level and duration, it is also evident that individuals exposed to the same noise exposure often develop significantly different amounts of noise-induced hearing loss (Burns & Robinson, 1970; Le Prell et al., 2012; Mills, Schulte, Boettcher, & Dubno, 2001; Passchier-Vermeer, 1987; Strasser, Irle, & Legler, 2003; Taylor, Pearson, Mair, & Burns, 1965).

Both temporary auditory injury (measured as a temporary threshold shift, TTS) and permanent auditory injury (measured as permanent threshold shift, PTS) can vary significantly across individuals. Consequently, there is long-standing, significant interest in what makes one person more or less vulnerable to hearing-loss than another, in order to identify (and ultimately, protect) high-risk individuals. Another important need for this explanation is to improve upon otoprotective agent clinical trial design; in order to confidently state that an agent does or does not protect against NIHL, it is important to first consider individually variable susceptibility to NIHL across participants and within groups. The significant efforts to investigate intrinsic, biological differences among individuals have revealed sex, race, genetics, cardiovascular health, and a host of other factors to be associated with NIHL vulnerability; however, these factors explain only a small portion of the large observed variance (see 2.1.1). As such, there is not yet a complete (or sufficient) explanation for the wide variation in degree of temporary threshold shift (TTS) and permanent threshold shift (PTS) observed in demographic studies of NIHL. The Organization for Standardization (ISO) specifies a method for estimating occupational, permanent hearing loss as a function of various sound-levels and durations of occupation (ISO 1999:2013); in these estimates, dramatic variability in observed in individual susceptibility to NIHL from occupational noise-hazard (see estimate below from ISO 1999:2013). Researchers continue to search for explanations as to what makes one individual biologically more vulnerable to auditory injury than another.

ISO 1999:2013. Variable Hearing Level Estimates After Varying Occupational Durations in a 100 dBA Environment



2.1.1 Confirmed Biologic and Social Factors Influencing NIHL Susceptibility

The significant efforts to investigate intrinsic, biological differences among individuals have revealed that many factors influence vulnerability, including race/ethnicity (Lin et al., 2012), education/socioeconomic status (Agrawal, Platz, & Niparko, 2008; Henderson, Testa, & Hartnick, 2011; Henderson et al., 2011), noise-exposure (Agrawal, Platz, & Niparko, 2009; Mahboubi et al., 2013; Zhan et al., 2011), smoking and secondhand smoke (Cruickshanks et al., 1998; Fabry et al., 2011), diabetes (Bainbridge, Hoffman, & Cowie, 2008), cardiovascular health (Agrawal et al., 2009; Nash et al., 2011), ototoxic drugs (Campbell & Le Prell, 2018) and genetic expression (Uchida, Sugiura, Ando, Nakashima, & Shimokata, 2011); for review, see (Liu & Yan, 2007). Although sex, race, genetics, cardiovascular health, and a host of other factors have statistically significant associations with NIHL vulnerability, these factors explain only a small portion of the large observed threshold (dB) variance, often fewer than 5 dB HL.

2.1.2 Possible Mechanical / Physiological Factors Influencing NIHL Susceptibility

Given that it is well-established that more noise means more risk, it stands to reason that individual variation in amplification from the external-ear, which results in higher sound-levels at the eardrum in some individuals than others, is likely to play a role in individual NIHL vulnerability. The current NIHL-risk models (namely, OSHA, 1983 and NIOSH, 1998), do not consider external-ear amplification when estimating NIHL-risk. This thesis proposes that the individual transfer function of the open ear (TFOE) and the transfer function of the earcanal (TFEC) should be considered as a mechanical, physiological factor, which could potentially explain a major portion of individual NIHL risk variation. TFOE is the total amount of amplification provided by the combined external-ear structures (i.e., pinna, concha bowl, earcanal). TFEC is a sub-measure of TFOE, in that it reflects the external-ear amplification solely from the earcanal structure. Fundamental physics drives the variability of individual TFOE and TFEC; the pinna, concha bowl, and earcanal structures are simply funnels and a resonator-tube closed at one end; the properties of these structures (primarily, size and shape) are uniquely different in each individual, as a function of the individual's body size and shape. TFOE could be associated with NIHL-risk during an open-ear (free-field) noise-exposure, as was once suggested by Shotland (1996). Shotland collected and modeled human TFOE amplitude, and observed an average of 9.8 dB-A with a standard deviation of 1.8 dB-A across 30 participants (19 female, 11 male); however, he did not measure participants' hearing sensitivity. Shotland advocated for the use of TFOE to identify those at greatest NIHL-risk based on a TFOE amplitude exceeding 2 standard deviations from the population mean. He further encouraged that dosimetry data be modified to reflect TFOE: for example, a 90 dB-A dosimetry measurement would be treated as a 105 dB-A exposure for an individual with a 15 dB-A TFOE. Separate from this suggestion that TFOE could influence NIHL-risk, the principal investigator also supports that TFEC could be associated with NIHL-risk during an ear-level noise-exposure; for example, using earbuds to listen to music, watch a movie, or play a video game; Portnuff (2017) has also suggested that individual-specific earcanal volume should be considered when calculating exposure level.

The most precise way to measure TFOE and TFEC relies on the invasive and technically skilled placement of a probe-microphone assembly inside the earcanal near the eardrum, subsequent to normal otoscopic examination of the ear. Thus, the process to obtain TFOE and TFEC is only feasible when specialized equipment and trained personnel are available. For this reason, the principal investigator (PI) suspects that even if it were confirmed that external-ear amplification influenced NIHL, Shotland's suggestion of incorporating TFOE into hearing conservation programs would be as challenging in 1996 as it would be today, in 2019, using the described measurement method. It would be helpful to identify non-invasive and non-technical proxy metrics of TFOE and TFEC that are feasible for implementation in hearing conservation programs and related efforts.

2.2 External-ear Resonance

2.2.1 Confirmed Effect of External-ear Resonance on Noise-Induced Audiometric Configuration

Notably, other groups have also explored the relationship of external-ear amplification and NIHL risk, though these groups have primarily focused on peak-SPL of the earcanal resonance frequency and the frequency of the subsequent noise-induced audiometric notch, rather than total amplification of the external-ear and overall NIHL-risk (Bruel, 1977; Caiazzo & Tonndorf, 1977; Gerhardt et al., 1987; Kuhn, 1979; Pierson et al., 1994, Price, 1979; Rodriguez & Gerhardt, 1991; Rosowski, 1991; Shaw & Vaillancourt, 1985).   Studies completed in the 1980s provided an explanation for the classic "notched" audiogram associated with NIHL based on the peak-resonance frequency of the earcanal (Gerhardt, et al. 1987, Rodriguez & Gerhardt. 1991, Pierson, et al. 1994). This work correlated the earcanal properties (e.g., length, volume, resonance) to the specific frequency (Hz) of the "notch" (i.e., select frequencies with reduced hearing sensitivity) observed in the audiogram, incurred by dangerous noise exposure. More specifically, larger volume earcanals were more likely to experience temporary threshold shift (TTS) notches at 3 kHz, while smaller volume earcanals were more likely to experience TTS notches at 6 kHz (Gerhardt et al., 1987). In Hellstom's study (1996), a similar pattern was observed with TTS at 2 kHz and 4 kHz, respectively. In regards to resonance, it appears that with every 100 Hz difference in maximum resonant frequency, the TTS notch shifts 140 Hz (Rodriguez & Gerhardt, 1991). Although these data document a relationship between peak-resonance of the earcanal and audiometric frequency at which TTS is observed, they do not directly demonstrate a continuum for NIHL-risk (i.e., dB of TTS) as a function of peak-resonance (nor TFOE - amplification from combined external-ear structures was not analyzed). Nonetheless, it is reasonable to hypothesize that if TFOE (total in-ear amplification) is larger, the total amount of corresponding hearing loss would also be greater. Again, there is widespread agreement that more noise means more NIHL risk.

2.2.2 Confirmed External-ear Resonance Variability Across Populations

Researchers have studied populations that deviate from an "average" earcanal peak-resonance patterns, but few studies have looked at TFOE (i.e., gain from the combined external-ear structures) deviation across populations. Hellstrom (1995) studied peak-resonance of the earcanal in 100 high school students relative to their hearing thresholds. The data showed that, regardless of sex, hearing thresholds were best at the peak-resonance of the earcanal. The data also showed that females tended to have higher frequency peak-resonance than males, attributed to generally smaller earcanal size. Bastos (2012) searched for differences both in earcanal peak-resonance and earcanal volume between age groups (adults vs. elderly participants), but found no significant correlations or differences between age groups (though, interestingly, average elderly eardrum compliance was .2 ml greater than adult eardrum compliance); this echoed the results of Park et al. (2008), Stenklev (2004), Uchida et al. (2000), and Rawool & Harrington (2007). However, observed in Bastos (2012) were statistically significant sex differences detected in peak-resonance, in that females had higher amplification at higher frequencies - a result that was attributed to smaller earcanal volumes in females, echoing Hellstrom's findings (1995). Previous work has demonstrated these significant differences in earcanal volume between males and females, with males having larger earcanal volumes on average (Barnes, Sabo, & Coelho, 2018; Wahab & Rashid, 2009).

Interestingly, Silva et al. (2014) observed the elderly adult population to have less gain in earcanal peak-resonance than the non-elderly adult population, suggested to be a consequence of mass-dominated changes in the aging earcanal. In Hellstrom's original, older cohort (1996) (20-60 years) from a roadside construction company, results suggested that earcanal length was positively correlated with both age and the peak-resonance of the earcanal. In the older population, hearing levels were positively correlated to a 1.25 kHz peak-resonance. Hellstrom concluded that length and volume of the earcanal increase as a function of age, thus lowering the peak-resonance of the earcanal. Taken together, the Hellstrom (1996) and Silva et al. (2014) results suggest that the elderly population not only has progressively lower peak-resonance amplification from the earcanal, but also a progressively lower peak-resonance frequency as a function of age.

Turning to the pediatric population, the earcanal grows and changes in resonance (lowering peak dB-SPL) until about 7-9 years of age (Sinclair et al., 1996); the dB-SPL is significantly higher inside of a child's earcanal than an adult's (Ballachanda, 1997). The relationship observed between smaller earcanal volume and greater real-ear to coupler difference measurement has also been observed in infants (Bingham, Jenstad, & Shahnaz, 2009). Further, this relationship has been shown to hold true in abnormally large earcanal volumes due to tympanic membrane perforations (Bingham et al., 2009) and open mastoid surgery (Martin, Munro, & Lam, 2001; Moryl, Danhauer, & DiBartolomeo, 1992).

2.3 Literature Summary and Gap

As detailed in the above text, the literature shows:

1) It is widely accepted that - holding duration of a noise exposure constant - the louder the sound-level, the more severe the subsequent hearing loss.

2) There are stark disagreements about the sound-level at which NIHL risk begins, the rate at which risk increases, and the line that is drawn regarding the "acceptable" amount of hearing loss.

3) There is no complete (or sufficient) explanation for the variable degree of TTS and PTS observed in demographic studies of NIHL.

4) It is known that the external-ear provides variable amounts amplification across individuals, and differs as a function of the mechanical / physiological structures of the external-ear.

Gaps in the literature:

It is reasonable to hypothesize that individuals with more external-ear amplification (i.e., higher TFOE, higher TFEC) will exhibit higher noise-exposure sound-levels inside of their ears, which could explain (at least in part) why individuals experience different amounts of hearing-loss when exposed to the same noise-insult. Presently, there are 2 gaps in the literature that this thesis will address. First, there is a need to document the extent of TFOE and TFEC variability - calculated as overall amplification (dB-A) from the external-ear structures - and test the hypothesis that this variability substantially influences an individual's in-ear noise-dose from an exposure. Second, there is a need to test for non-technical, non-invasive proxy metrics of TFOE and TFEC, in order to move towards a hearing conservation effort in which it is feasible to include TFOE and TFEC in individual NIHL-risk calculation.

CHAPTER 3

PRELIMINARY RESEARCH

This study was approved by the Institutional Review Board at the University of Texas at Dallas. Signed consent forms were obtained from participants prior to study enrollment. Participants were recruited from the University of Texas at Dallas campus in Richardson, Texas and the Callier Center for Communication Disorders in Dallas, Texas. All study procedures were performed using dedicated clinical research equipment located at the Callier Center for Communication Disorders in Dallas, TX. All study procedures were conducted by an audiologist or AuD graduate students in the Doctor of Audiology program at UT Dallas. Participants were allowed to withdraw at any time.

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Abstract

NIHL risk is estimated using a “noise-dose” obtained during an exposure; noise dose is mathematically derived from the sound-level and duration of the exposure. Typically, sound-levels are measured in the environment of the exposure with a sound-level meter, or with a dosimeter (a portable, personal sound-level meter) clipped on to the individual’s body. However, it is known that sound measured inside the ear is louder than sound outside the ear, as

a function of external-ear amplification. A feasibility study was conducted to test the hypothesis that 1) in-ear sound-level of an exposure could be reliably measured using a probe-microphone assembly and extrapolated to individual NIHL-risk, and 2) in-ear sound-level could be reliably estimated by proxy metrics of external-ear properties (e.g., pinna size, earcanal size, eardrum compliance, middle ear pressure).

48 participants bilaterally (42 female, 6 male) were enrolled who met the criteria of <10% cerumen occlusion and typically formed pinnae and earcanals. Participants underwent bilateral otoscopy, tympanometry, pinnae measurement, and external-ear amplification measurements. Individual external-ear amplification was documented. Sex differences, right and left ear differences, Run 1 to Run 2 repeatability differences, pinna size differences, and external-ear amplification differences across multiple sound-levels were analyzed. Proxy metrics of external-ear amplification were tested using linear regression modeling.

External-ear amplification from the combined structures ranged from 5-15 dB-A. There were no statistically significant right and left ear differences, Run 1 to Run 2 repeatability differences, pinna size differences, or external-ear amplification differences across multiple sound-levels. The study was not powered to detect sex differences. Multiple proxy measurements of body size were correlated to external-ear amplification; however, the only statistically significant correlation was eardrum compliance (ml).

External-ear amplification from the combined structures (i.e., pinna, concha, earcanal) is highly variable across individuals (though this dataset was very homogeneous; 42/48 adult females), and can be reliably measured with this real-ear measurement study design. Eardrum compliance could serve as a proxy metric for external-ear amplification; however, this needs correlation to be tested in a new cohort with equal females and males, and across multiple age groups, in order to be confident in its validity.

3.1 Specific Aims

1. Test the hypothesis that participants will exhibit external-ear amplification variable enough to create reasonable doubt that personal dosimetry reveals accurate individualized NIHL-risk.
2. Test the hypothesis that this study design is feasible, in that all measurements are reliably repeatable, and that external-ear amplification increases linearly with increasing stimulus sound-level.
3. Test the hypothesis that external-ear amplification is reliably correlated with pinna size, earcanal volume, eardrum compliance, suggesting that these could serve as proxy metrics of TFOE.

3.2 Methods

3.2.1 Participants

Participants included 48 adults (self-identified as 42 female, 6 male), ranging in age from 21-60 years. All participants met the study enrollment criteria, including clear otoscopic examination bilaterally (full visualization of the tympanic membranes with no apparent abnormalities and <

10% cerumen occlusion), and Type A tympanograms, using a 226 Hz probe tone. Participants were mainly adult students and faculty affiliated with the audiology program at UT Dallas. Demographic information was obtained from participants via a questionnaire administered online using Qualtrics Research Core survey platform (Qualtrics, Inc., Seattle, WA).

3.2.2 Otoscopy

Visual examination of the earcanal and tympanic membrane was conducted to assess the presence of debris, abrasion, or cerumen. Normal otoscopic outcomes were defined as full visualization of the tympanic membrane with no apparent abnormalities and < 10% cerumen occlusion, as excess cerumen has been shown to alter probe-microphone measurements (Gerling, Boester, & Yu, 1997). If participants did not meet this otoscopic criterion, they were not enrolled in the study.

3.2.3 Tympanometry

Tympanometric measures were used to assess equivalent earcanal volume (cc), eardrum compliance (ml), and peak middle-ear pressure (daPa), using a Grason Stadler Instruments TympStar Pro in compliance with ANSI S3.39 and IEC 601-1 criteria. Data was later excluded for participants who exhibited tympanometry outside of normal limits (defined as “Type A” with 226 Hz probe tone, middle ear pressure ranging -200 to +200 daPa). To standardize probe-insertion depth, the probe size was selected such that the earcanal was sealed when the base of the probe was flush with the opening of the earcanal. If a seal could not be obtained when the probe base was in this position, the probe was replaced with a larger size. It was important to control probe depth to reduce the likelihood that the probe would artificially inflate or deflate the equivalent earcanal volume; a probe tip pushed too far into the earcanal will artificially deflate its volume (cc) (Gerling & Goebel, 1992; Gerling et al., 1997).

3.2.4 Transfer Function of the Open Ear Measurement

The Audioscan Verifit-2 was calibrated for on-ear speech-mapping measures, and the internal "pink-noise" stimuli was selected. A series of three pink-noise stimuli were presented at varying intensities, in order to assess the linearity of TFOE across stimulus levels; pink-noise carries equal energy at each octave, and is commonly used to assess hearing protection effectiveness against dangerous sound-levels. Pink-noise stimuli were presented at 60, 65, and 70 dB-SPL, which were equivalent to 58, 63, and 68 dB-A, after applying A-weighting. TFOE measurement was performed bilaterally using the Audioscan Verifit-2 probe-microphone system, including the use of Audioscan probe-microphones. Participants sat approximately 2 ft from the free-field speaker source at 0 degrees azimuth. When testing TFOE bilaterally, the software provides feedback that facilitates the centering of the participant's ears in the free-field, such that bilateral sound-levels are equal at the reference-microphones on each ear. All in-ear measurements are recorded bilaterally and simultaneously. The Verifit-2 is designed to automatically calibrate the desired presentation sound-level using the reference-microphones, which are suspended inferiorly to the participant's pinnae lobules.

TFOE measurement involved two microphones (see Figure 1): 1) reference-microphones, which sits at the base of the ears just inferior to the pinnae lobules and measure free-field sound-level, and 2) probe-tubes connected to microphones which measure in-ear sound-levels, near the eardrum. The average adult earcanal length is 25 mm, and the average distance between the earcanal opening and the intertragal notch is 10 mm; as such, a probe tube placed 30 mm past the tragus will land within 5 mm of the adult eardrum (Hawkins, Alvarez, & Houlihan, 1991); this placement provides accuracy within 2 dB-SPL of the true SPL measurement at the eardrum (Dirks, Donald D. & Kincaid, 1987). Per the Verifit-2 manual, probe-microphones were marked at 28 mm for females and 30 mm for males. Probe-tubes were placed into the open earcanals with aforementioned markers resting at the intertragal notch - this measurement method is consistent with the widely used "constant insertion" method, which reduces variability in the measurement (Dirks, Donald, Ahlstrom, & Eisenberg, 1996; Hawkins & Mueller, 1986; Seewald, 1991, Moodie et al., 1994; Seewald, 1991). Studies have shown highly repeatable test-retest reliability using this measurement in children and adults (Sinclair et al., 1996), within even 1 dB of error (Munro & Davis, 2003). TFOE measurements were repeated bilaterally after removal and reinsertion of probe tube microphones.

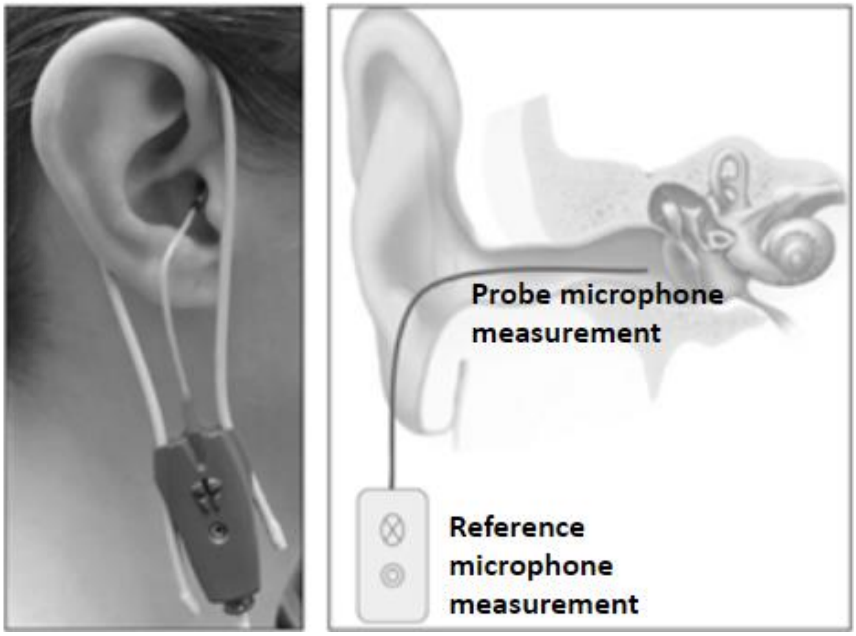

Figure 1.

TFOE measurement setup. RECD measurement setup was identical to TFOE, with the exception of the stimulus presentation via an ER-3A insert-earbud placed in the earcanal (not pictured), as opposed to TFOE stimulus presentation via free field speaker.

3.2.5 Transfer Function of the Open Ear Calculation

The difference in sound-level (dB-A) between the reference-microphone (suspended inferior to the pinna lobule) and the microphone connected to the probe-tube (resting inside the open ear near the tympanic membrane) is the amount of total amplification from the structures of the external-ear (e.g., pinna, concha bowl, earcanal) (see Figure 1).

3.2.6 Transfer Function of the Earcanal (TFEC) Sound-Level / Real-Ear to Coupler Difference (RECD) Overall Sound-Level Measurement

RECD measurement is an occluded-ear measurement that is normally used to assess the deviation of a patient's earcanal resonance from that of the "average" earcanal resonance of similarly aged individuals; normally (i.e., clinically), this measurement is performed to guide individual adjustments to hearing aid amplification programming. However, in this study, the focus is not on the earcanal's peak-frequency resonance, but instead on the *overall* sound-level (dB-A) measured inside of the ear (assessing external-ear amplification from the earcanal), when a pink-noise stimulus is presented through an insert-earphone. Measurement setup is very similar to TFOE, except that the pink-noise stimulus (approximately 53 dB-SPL as measured in 1/12 octave bands .2 -12.5 kHz, inside a 2.0 cc coupler) is presented to the participants' ears through an ER-3A insert-earphone, instead of through the free-field. The extent to which the TFEC was different than the 53 dB-SPL measured in the 2.0 coupler indicates the extent of external-ear amplification solely attributed to earcanal amplification.

The TFEC sound-level was recorded to determine its relationship to the TFOE. Though the TFOE stimulus (pink-noise) and the TFEC stimulus (pink-noise) differed in presentation sound-level, this does not impact absolute amplification, which is constant across various presentation levels. Taken together, TFOE was used as a measurement of total external-ear amplification, whereas TFEC was used to isolate and measure solely the earcanal contribution of TFOE amplification. Higher TFEC overall sound-level measurements should be correlated with higher TFOE measurements. In other words, if an individual exhibited a high occluded-ear sound pressure level, it was expected that the individual would also exhibit a high open-ear sound pressure level, as earcanal amplification is part of the open-ear variance.

3.2.7 Data Extraction and dB-A Transformation

Fast Fourier Transformation (FFT) of the data was completed in 1/12 octave steps from 200 – 12,500 Hz, and the data from the Verifit-2 were extracted via the “Export Session” feature. The exported files were then loaded into the manufacturer’s Excel spreadsheet, “Audioscan Template”, which provides the reference microphone and probe microphone sound-level measurements (FFT results) in 1/12th octave steps from 200 - 12,500 Hz. The Audioscan Verifit-2 system presents and measures unweighted sound-levels (dB-SPL); however, the NIHL-risk tables are based on A-weighted sound-levels. As such, the FFT measured in dB-SPL at the reference- microphone and at the probe-microphone were manually transformed from dB-SPL to dB-A by applying the A-weighted correction factors listed in the OSHA Technical Manual (OSHA, 1990). These correction factors are derived from the 40-phon equal-loudness contours of the Fletcher-Munson curves (Fletcher & Munson, 1933). Overall dB-A for TFOE and TFEC were calculated as the summed energy at 0.25, 0.5, 1, 2, 3, 4, 6, 8, 10, and 12.5 kHz.

3.2.8 Pinna Size Measurements

Pictures of the right and left pinna were taken and measured from points A-B and C-D using ImageJ computer software (Figure 2).

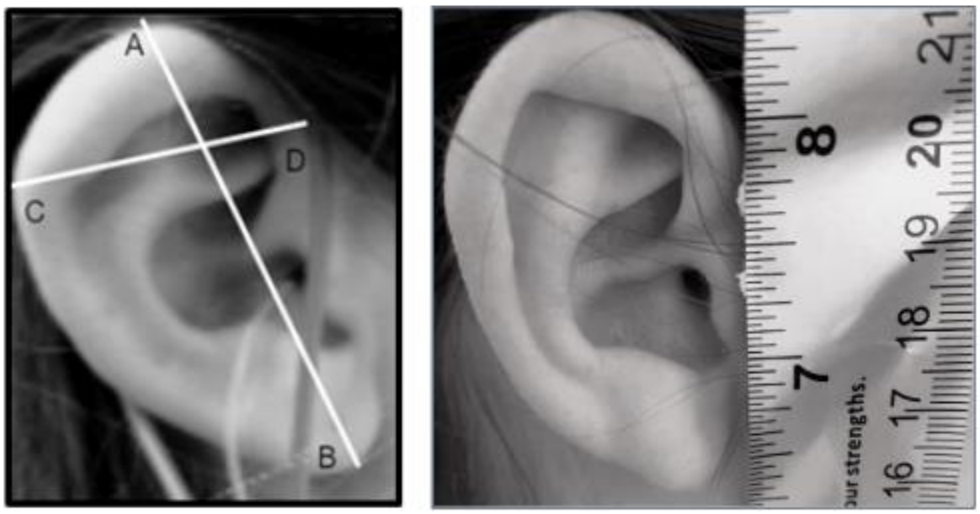

Figure 2.

Pinna height and width measurements were analyzed in ImageJ software. Marker points were digitally placed according to anthropometric pinna measurement methods (Sharma. 2016).

3.2.9 Experimental Flow

Informed consent was obtained from each participant, all of whom were adults (18+ years). Otoscopy was performed. Pictures of the pinnae were taken bilaterally to be later analyzed in ImageJ software. Tympanometry was performed and repeated bilaterally. TFOE and TFEC were performed and repeated bilaterally. A demographic questionnaire was completed by participants.

3.3 Statistical Analyses

3.3.1 Right and Left Ear Differences

Right and left ear differences in equivalent earcanal volume, eardrum compliance, middle-ear peak-pressure, TFEC overall sound-level, and TFOE were assessed using Paired T-tests.

3.3.2 Test-retest Reliability

Test-retest reliability of equivalent earcanal volume, eardrum compliance, middle-ear peak-pressure, TFEC overall sound-level, and TFOE measurements were assessed using Paired T-tests.

3.3.3 Differences in Stimulus Presentation Levels

The effect of stimulus presentation level (58, 63, and 68 dB-A pink-noise) on TFOE amplitude was assessed using one-way ANOVA.

3.3.4 Sex Differences

Sex differences in height, equivalent earcanal volume, eardrum compliance, middle-ear peak-pressure, TFEC overall sound-level, and TFOE measurements were assessed using one-way ANOVAs.

3.3.5 Estimating the Transfer Function of the Open Ear with Proxy Metrics

The ability to reliably estimate TFOE was assessed using multiple regression analysis with independent variable factors including: equivalent earcanal volume, eardrum compliance, TFEC overall sound-level, pinna width, pinna height. Simplified linear regression was later performed to assess whether TFOE could be reliably estimated using a single factor from the aforementioned list.

3.3.6 Estimating TFEC with Proxy Metrics

TFEC (transfer function of the earcanal) estimation using proxy metrics was assessed using multiple linear regression analysis with independent variable factors including: equivalent earcanal volume and eardrum compliance. The specific aim regarding TFEC was to be able to estimate it with a single-factor linear regression from the aforementioned list; thus, single-factor linear regression analyses were also performed.

3.4 Results

3.4.1 Right and Left Ear Differences

No statistically significant differences were found between right and left ears in any variable measured (equivalent earcanal volume, middle-ear peak-pressure, eardrum compliance, TFEC overall sound-level (dB-A), pinna width, pinna height, and TFOE) ($p > .05$). As such, subsequent analyses used averaged bilateral measurements.

3.4.2 Repeatability of Measurements: Run 1 vs. Run 2

Measurement repeatability from Run 1 to Run 2 was analyzed separately for the left and right ears for the following variables: equivalent earcanal volume (cc), eardrum compliance (ml), middle-ear peak-pressure (daPa), TFEC (dB-A), and TFOE at 58, 63, and 68 dB-A. For the right ear, small but statistically significant differences were observed in some measures; Table 2 shows a statistically significant difference in equivalent earcanal volume; descriptive analyses (Table 3) show the means of Run 1 and Run 2 to be extremely close (1.32 cc and 1.36 cc); these statistically significant differences are not clinically significant. For the left ear, statistically significant differences between Runs 1 and 2 were observed for eardrum compliance and TFOE when presented at 58 dB-A (Table 2); descriptive analyses (Table 3) show the means of both measurements to be extremely close (eardrum compliance means = .68 and .72, and TFOE 58 dB-A means = 70.07 and 69.40), indicating that these statistical differences are not clinically significant. Multiple comparisons were not corrected, as the number of comparisons was small and pre-planned. Repeatability was high for all variables; an average of Run 1 and Run 2 was used for all variables in subsequent analyses.

Table 2.

Paired Samples Test - Run 1 vs. Run 2. Bolded values indicate statistical significance at $p < .05$.

Paired T-Test Results Assessing Run 1 & Run 2 Repeatability

Ear	*Pair*	*Lower*	*Upper*	*t*	*Sig. (2-tailed)*
Left	Volume - Run 1 & Run 2	-0.05	0.03	-0.64	0.52
Right	Volume - Run 1 & Run 2	-0.07	-0.01	-2.45	**0.02**
Left	Compliance - Run 1 & Run 2	-0.07	-0.01	-2.55	**0.01**
Right	Compliance - Run 1 & Run 2	-0.06	0.00	-1.92	0.06
Left	Pressure - Run 1 & Run 2	-1.11	9.93	1.61	0.11
Right	Pressure - Run 1 & Run 2	-5.43	4.65	-0.16	0.88
Left	TFEC Sound-Level dBA - Run 1 & Run 2	-0.23	0.32	0.33	0.74
Right	TFEC Sound-Level dBA - Run 1 & Run 2	-0.28	0.42	0.40	0.69
Left	TFOE 58 dBA - Run 1 & Run 2	0.02	1.32	2.07	**0.04**
Right	TFOE 58 dBA - Run 1 & Run 2	-0.65	0.81	0.21	0.83
Left	TFOE 63 dBA - Run 1 & Run 2	-0.15	0.90	1.43	0.16

Right	TFOE 63 dBA - Run 1 & Run 2	-0.76	0.37	-0.69	0.49
Left	TFOE 68 dBA - Run 1 & Run 2	0.01	1.12	2.04	0.05
Right	TFOE 68 dBA - Run 1 & Run 2	-0.43	1.14	0.91	0.37

Table 3.

Descriptive statistics for statistically significant measurements from Table 2.

Descriptive Statistics Analysis of Statistically Significant Run 1 & Run 2 Differences

Ear	*Pair*	*Mean*	*Std. Deviation*
Right	Volume - Run 1	1.32	0.38
Right	Volume - Run 2	1.36	0.36
Left	Compliance - Run 1	0.68	0.36
Left	Compliance - Run 2	0.72	0.37
Left	TFOE 58 dB-A - Run 1	70.07	2.60
Left	TFOE 58 dB-A - Run 2	69.40	3.38

3.4.3 TFOE Variability with Increasing Pink-Noise Sound-Level

No significant differences in TFOE were observed when the level of the pink-noise stimulus was systematically manipulated across 58, 63, and 68 dB-A presentation levels (p >.05). In other words, if a participant's TFOE was 8 dB-A when measured using a 58 dB-A pink-noise stimulus (58 dB-A presented +8 dB TFOE gain = 66 dB-A probe-microphone sound-level), the participant's TFOE was also 8 dB-A when measured using a 63 dB-A pink-noise stimulus (63 dB-A presented +8 dB TFOE gain = 71 dB-A probe-microphone sound-level) (Figure 3). As no statistically significant change in TFOE was observed across stimulus levels, subsequent analyses were limited to the 68 dB-A pink-noise condition.

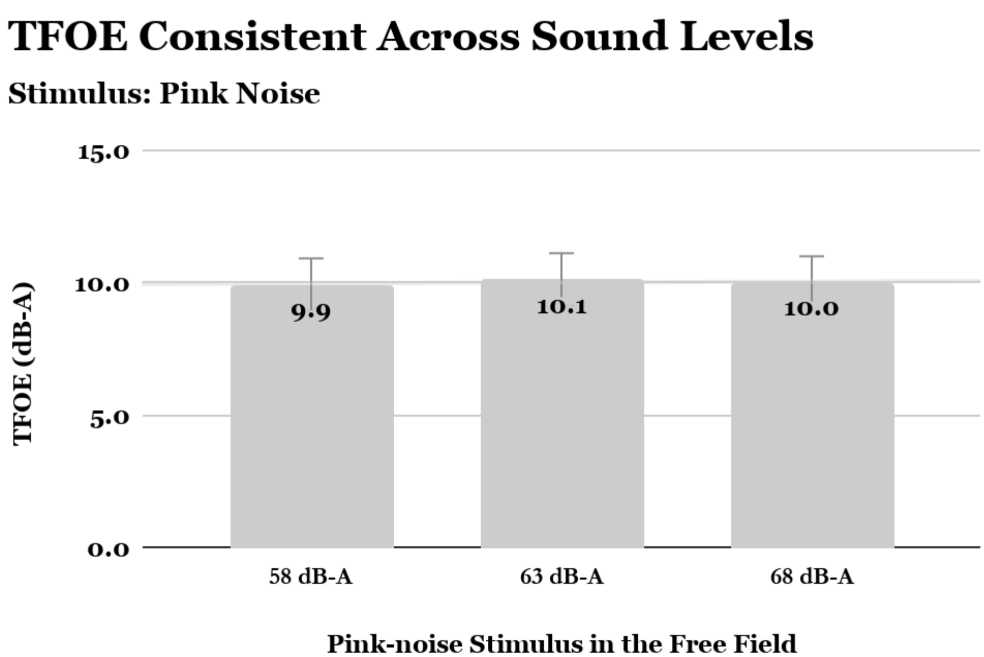

Figure 3.

The average TFOE across participants was 10 dB-A; error bars show standard deviation around the mean. On average, TFOE did not change as a function of increasing free-field presentation level (p >.05).

3.4.4 Sex Differences

No significant differences were found between females and males in middle-ear peak-pressure, eardrum compliance, TFEC overall sound-level, or TFOE (p >.05); however, the study was not sufficiently powered to detect sex differences, and so these results should be interpreted with caution. Significant sex differences were found in height, equivalent earcanal volume, pinna height, and pinna width (p <.05). However, due to the small number of males in this dataset (6M, 42F), male and female data were combined for multiple regression analyses. Statistically significant sex differences and descriptive statistics for all variables across females and males are shown in Table 4.

Table 4.

Descriptive statistics for all bilaterally averaged variables, and one-way ANOVA analysis of sex differences. Bolded values indicate statistically significant differences at $p < .05$.

	ECV (cc)	TMC (ml)	MEP (daPa)	TFOE (dB-A)	TFEC (dB-A)	Height (in)	PinnaHorz (in)	PinnaVert (in)
Mean	1.3	0.7	15.9	9.9	68.8	60.4	1.4	2.4
SD	0.4	0.3	17.9	2.5	1.4	19.1	0.2	0.2
Range	1.5	1.4	108.8	10.2	6.7	13.0	0.9	0.9
Sex Diffs	**p = .01**	p = .18	p = .93	p = 0.60	**p < 0.08**	**p < .001**	**p = .03**	**p = .01**

*ECV = earcanal volume, TMC = tympanic membrane compliance, MEP = middle ear pressure, TFEC = transfer function of the earcanal, PinnaHorz = pinna width, PinnaVert = pinna height.

3.4.5 Individual Variability in Transfer Function of the Open Ear

Average TFOE in this study was 10 dB-A, ranging from 5 - 15 dB-A (Figure 4). Given that noise-dose is suggested to double in either 3-dB (NIOSH, 1998) or 5-dB (OSHA, 1983) increments, the observed variability suggests the potential for major differences in vulnerability to noise injury; if true, TFOE differences could have significant implications for the accuracy of NIHL dose calculation and associated risk-assessment efforts.

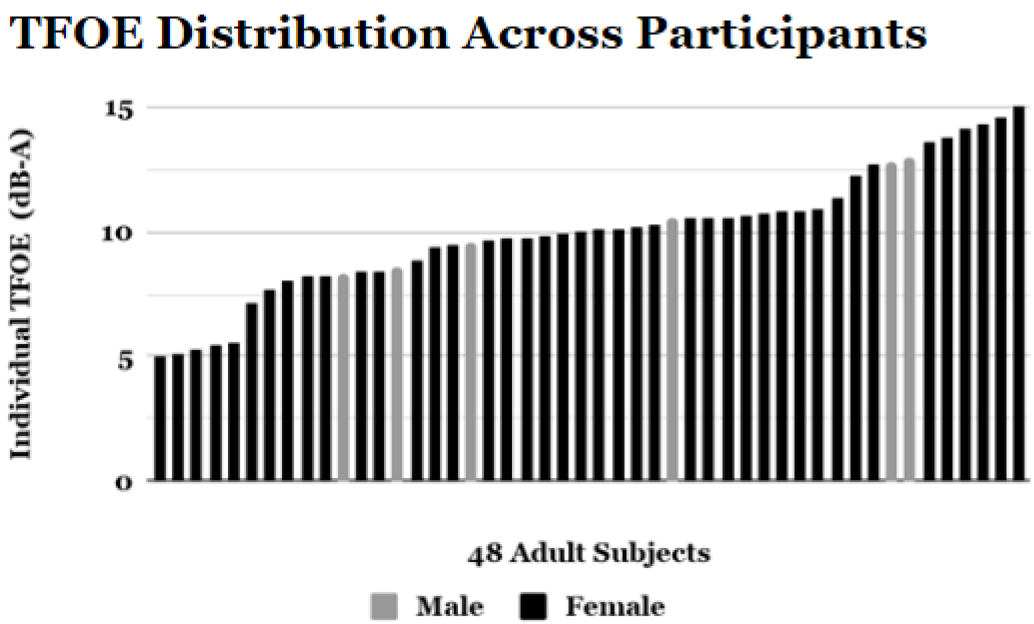

Figure 4.

TFOE (i.e., total external-ear amplification) varied significantly across the 48 participants, with amplification ranging from 5 - 15 dB-A (mean = 10 dB-A).

3.4.6 TFEC as a Proxy Metric of TFOE

As a single factor, TFEC (dB-A) reliably estimated individual TFOE (dB-A) (p =.009, R=.38, R^2=.15, see Table 5) (Figure 5). As TFEC overall sound-level increased, TFOE increased. The observed relationship had a medium effect size (F^2=.18, power = .81).

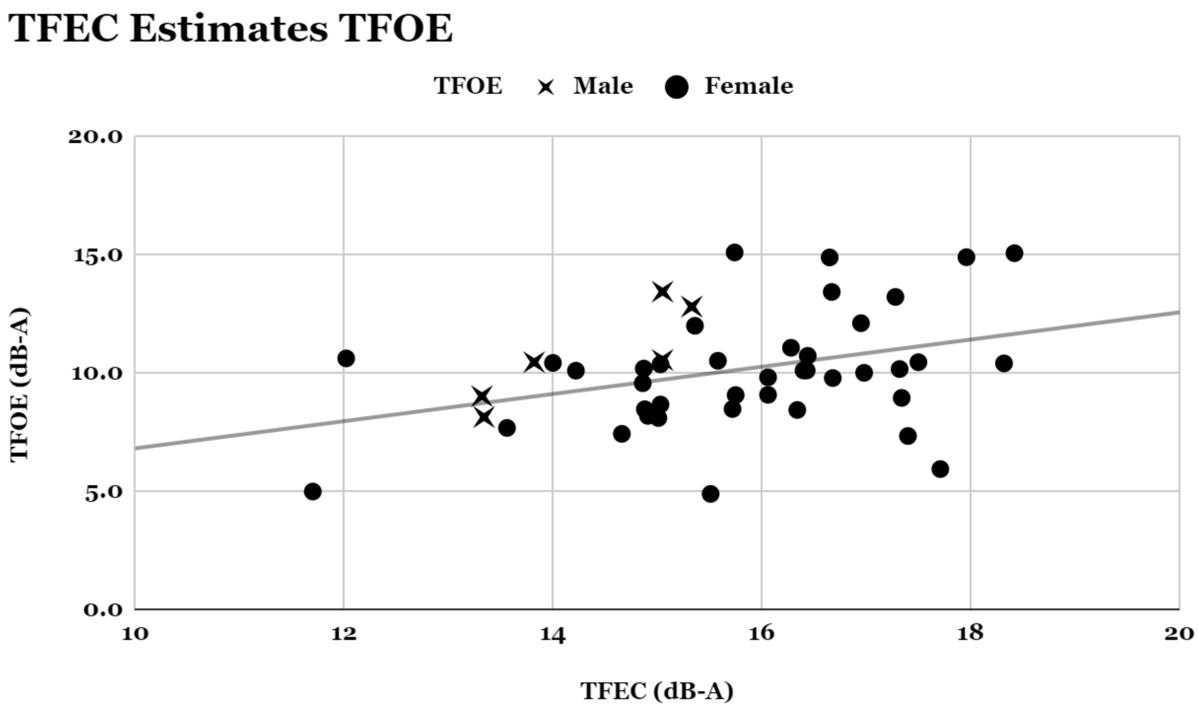

Figure 5.

There was a statistically significant relationship between TFEC and TFOE in this dataset, with higher TFEC values significantly correlated with higher TFOE values.

Table 5.

TFEC is reliably correlated with TFOE. Bolded values indicate statistical significance at $p < .05$.

Linear Regression Results - TFEC Estimates TFOE

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Sig. F Change
1	0.383a	0.15	0.13	2.16	**0.01**

a. Factors: RECD dB-A

3.4.7 Eardrum Compliance as a Proxy Metric of TFOE

As a single variable, eardrum compliance (ml) reliably estimated individual TFOE in this homogeneous dataset (p =.005, R=.40, R^2=.16, see Table 6) (Figure 6). As eardrum compliance increased, TFOE decreased. The observed relationship between eardrum compliance and TFOE had a medium effect size (F^2=.19, power = .84).

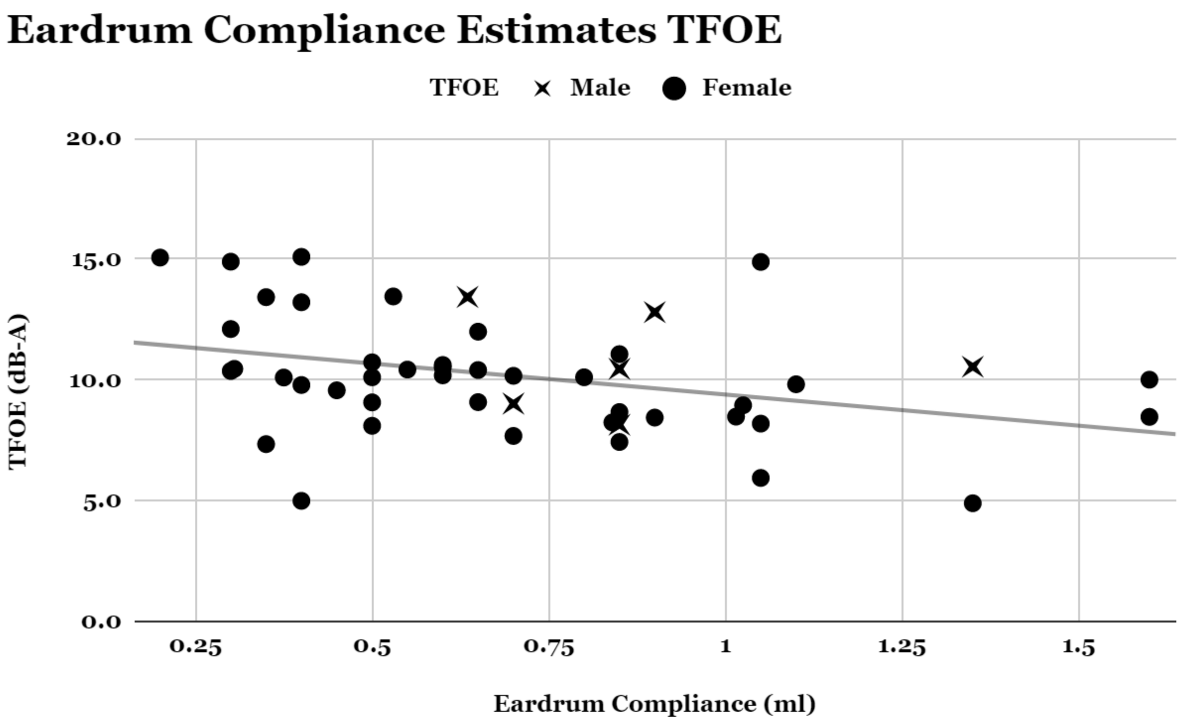

Figure 6.

There was a statistically significant relationship between eardrum compliance and TFOE measurement in the homogenous, preliminary dataset, with more compliant eardrums reliably correlated with lower TFOE.

Table 6.

Eardrum compliance was reliably correlated with TFOE in this dataset. Bolded values indicate statistical significance at $p < .05$.

Linear Regression Results - Eardrum compliance estimates TFOE

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Sig. F Change
1	0.40a	0.16	0.14	2.25	**0.005**

a. Factors: eardrum compliance (ml)

3.4.8 Earcanal Volume as a Proxy Metric of TFEC

When the TFEC pink-noise stimulus was presented to the ear via ERA-3 insert-earphone, the overall sound-level measured inside of the earcanal ranged from 11-18 dB-A across participants. This type of measurement is exclusively influenced by the amplification from the earcanal, as opposed to the larger amplification conferred by the entire external-ear structure. The linear regression model containing factors equivalent earcanal volume, middle-ear pressure, and eardrum compliance were significantly correlated with TFEC; however, only the earcanal volume coefficient was statistically significant. A refined linear regression model containing earcanal volume as the sole factor estimating TFEC maintained statistical significance (R=.43, R^2=.18, p <.05) (Table 7). As earcanal volume increased, TFEC decreased (see Figure 7).

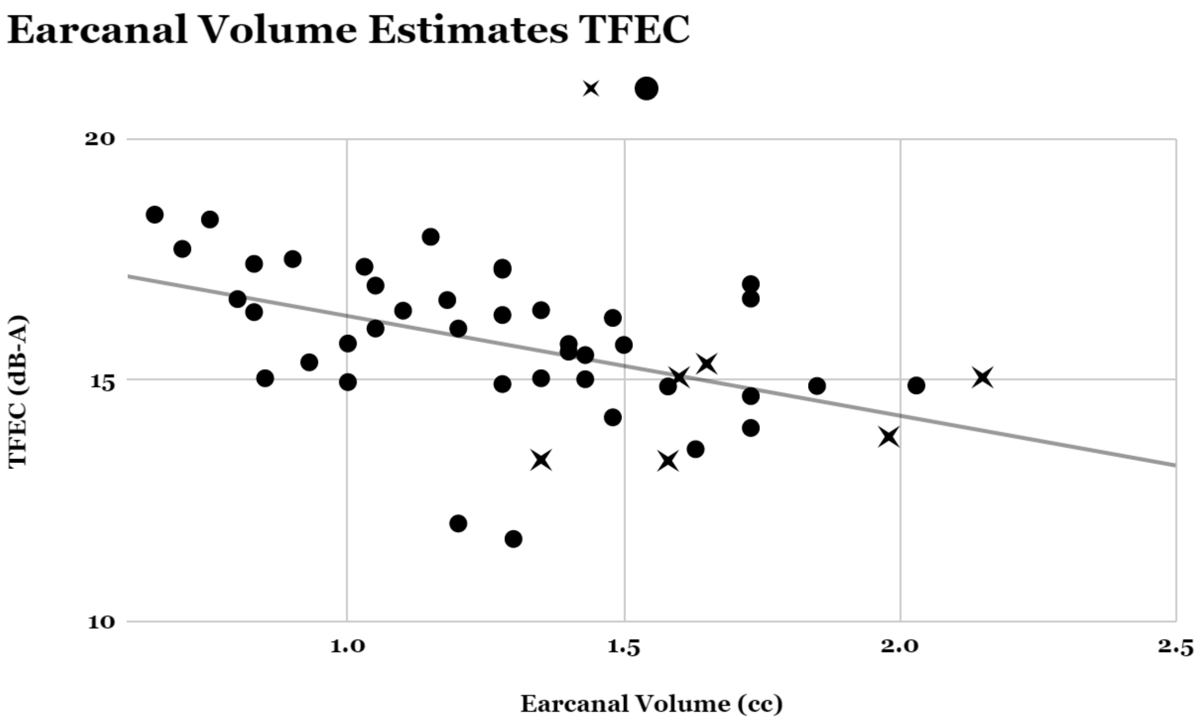

Figure 7.

There was a statistically significant relationship between earcanal volume (cc) and TFEC sound-level, with smaller equivalent earcanal volumes reliably associated with higher TFEC.

Table 7.

Equivalent earcanal volume served as a reliable proxy metric in estimating TFEC. Bolded values indicate statistical significance at $p < .05$.

Linear Regression Results - Earcanal Volume Estimates TFEC

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Sig. F Change
1	0.428a	0.18	0.17	1.39	**0.003**

a. Factors: earcanal volume

3.5 Conclusions and Next Steps

The individual transfer function of the earcanal (TFEC) was highly variable, ranging from 11-18 dB-A. The transfer function of the open ear (TFOE) was observed to be highly variable across individuals (5 - 15 dB-A). With this preliminary data in hand, it is confidently proposed that TFOE has the potential to substantially explain why individuals exposed to the same noise insult can develop significantly different amounts of temporary and permanent hearing threshold shift, given that more noise means more risk. In this dataset, the less technical and less invasive eardrum compliance (ml) tympanometric measurement proved to be a viable proxy metric for individual TFOE, with more compliant eardrums yielding lower TFOEs; this result should be interpreted with caution, as the preliminary dataset is highly homogenous (42 female, 6 male). Perhaps this finding is explained by the physics of the external and middle-ear: a more compliant (retracted) eardrum during sound-exposure means more space within the earcanal for sound pressure to disperse, yielding a lower overall sound pressure level, and thus, lower TFOE. Although the sample was predominantly adult and female, the TFOE data are highly consistent with those of Shotland (1996), and provide additional support for suggestions that TFOE (or, proxy metrics of TFOE) could be used to improve the precision of individual NIHL dose calculation and subsequent risk assessment.

In conclusion, individual variation in TFOE and TFEC could - at least in part - explain why individuals show considerably different NIHL when exposed to the same free-field or ear-level sound-exposure; this is especially convincing considering that NIHL risk doubles with every 3-5 dB-A sound-level increase. Further investigation of individual TFOE and TFEC variability is in order (namely, in a more heterogeneous dataset), to determine if TFOE and TFEC have the potential to identify high-risk NIHL populations, in addition to seeking proxy metrics grounded in theoretical basis.

On one end of the spectrum, the pediatric population is of interest to be included in a heterogeneous dataset, given that the earcanal grows and changes in resonance until about 7-9 years of age (Sinclair et al., 1996), and that the dB-SPL is significantly higher inside of a child’s earcanal than an adult’s (Ballachanda, 1997). The relationship observed between smaller earcanal volume and greater occluded-ear pink-noise measurement has also been observed in infants (Bingham, Jenstad, & Shahnaz, 2009). On the other end of the spectrum, the addition of adult male earcanals is of interest, as a function of their larger size. The relationship of larger earcanal volumes and lower occluded-ear sound-levels has been shown to hold true in abnormally large earcanal sizes as a function of tympanic membrane perforations (Bingham et al., 2009) and open mastoid surgery (Martin, Munro, & Lam, 2001; Moryl, Danhauer, & DiBartolomeo, 1992).

In a secondary study, the specific aims were to study the preliminary dataset's independent variables (those possibly correlated with TFOE and TFEC) in a heterogeneous sample with equal adult and pediatric males and females. The linear regression models obtained from this new, heterogeneous dataset will then be tested in a separate cohort to compare estimated TFOE and TFEC values to measured TFOE and TFEC values.

CHAPTER 4

MODELING INDIVIDUAL NIHL RISK WITH PROXY METRICS OF EXTERNAL-EAR AMPLIFICATION

This study was approved by the Institutional Review Board at the University of Texas at Dallas. Signed informed consent forms were obtained from adult participants prior to study enrollment; parental consent forms were obtained for the pediatric population (< 18 years), and informed, signed assent forms were obtained from participants age 7-17 years. Participants were recruited from the University of Texas at Dallas campus in Richardson, Texas, the Callier Center for Communication Disorders in Dallas, Texas, local secondary education schools, and UT Dallas social media pages. All study procedures were performed using clinical research equipment. All study procedures were conducted by an audiologist or AuD graduate students in the Doctor of Audiology program at UT Dallas. Participants were allowed to withdraw from the study at any time.

This secondary study in the dissertation research was funded by the Texas Speech and Hearing Foundation Research Grant (SG). AuD research assistants were funded by the Emilie and Phil Schepps Professorship in Hearing Science (CL).

4.1 Specific Aims

1. Test the hypothesis that significant group differences will reveal higher TFOE in adult females than adult males.
2. Adolescent male and female TFOE measurements will not significantly differ from adult male and female TFOE measurements.
3. The pediatric group will exhibit higher TFOE, irrespective of sex, than the adult and female adult and adolescent groups.
4. Eardrum compliance and TFEC will both estimate 95% of individual TFOEs within 5 dB-A accuracy.

4.2 Methods

4.2.1 Participants

158 total participants were enrolled in this study. 3 age groups of participants were recruited: pediatric (4-8 years), adolescent (13-17 years), and adult (18+ years). The distribution of participants is shown in Figure 8.

Inclusion: 1 normal, healthy pinna and earcanal without anatomical abnormalities or abrasions, and less than 10% cerumen occlusion in the earcanal (determined by trained research personnel).

Exclusion: Pinnae with anatomical abnormalities or abrasions, and greater than 10% cerumen occlusion in the earcanal, as determined by trained research personnel. Participants with excessive cerumen did not receive cerumen management; they were excluded from the study and advised to contact a medical provider regarding cerumen management. Participants exhibiting characteristics of a Type C tympanogram (negative middle ear pressure < -200 daPa) or a Type B tympanogram (non-compliant eardrum) were not excluded from enrollment criteria; however, they were later excluded as outliers from data analyses as a precautionary measure.

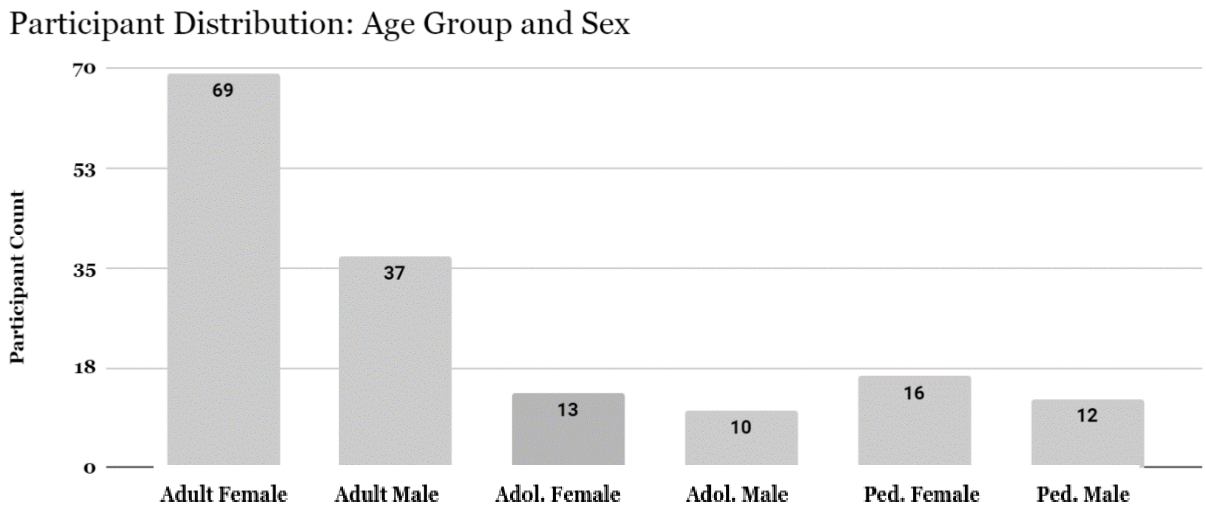

Figure 8.

Participant sex distribution within age group.

4.2.2 Otoscopy

Visual examination of the earcanal and tympanic membrane was conducted to assure normal anatomy and no presence of debris. Normal otoscopic outcomes were defined as full visualization of the tympanic membrane with no apparent abnormalities, including cerumen that would impede full visualization of the tympanic membrane, as excess cerumen has been shown to alter real-ear-unaided-gain probe-microphone measurements (Gerling, Boester, & Yu, 1997). Trained research personnel determined if cerumen is of any quantity exceeding 10% cerumen occlusion. If participants exhibited excessive cerumen, they were excluded from the study; cerumen management was not performed.

4.2.3 Tympanometry

Tympanometric measures were used to assess the functional status of the middle-ear with a Grason Stadler Instruments TympStar Pro in compliance with ANSI S3.39 and IEC 601-1 criteria. Normal middle-ear function was defined as Type A 226 Hz tympanograms bilaterally; while this was not a criterion for participant enrollment, participants exhibiting tympanometric results outside Type A were treated as outliers and excluded from analyses. It was important to control for inflated or deflated earcanal volume; pushing a probe farther in the earcanal would yield an artificially smaller volume measurement (Gerling & Goebel, 1992; Gerling, Boester, & Yu, 1997). To standardize probe insertion distance, researchers carefully selected the probe size that would seal the canal when the base of the probe was flush with the opening of the earcanal in the concha bowl.

4.2.4 Real-Ear Measurement Equipment and Setup

All real-ear probe-microphone measures was performed using the Audioscan Verifit 2 probe-microphone system, including Audioscan probe-microphones and ER-3A insert earphone for real-ear-to-coupler (RECD) measurements (i.e., Transfer Function of the Earcanal measurement, "TFEC"). Probe-microphones were marked at 20 mm for pediatric participants (<12 years), 28 mm for adolescent and adult females (>12 years, and 30 mm for adolescent and adult males (>12 years); probe-tubes were placed into the earcanal, with aforementioned markers resting at the intertragal notch (see Figure 9). This measurement method is consistent with the widely used "constant insertion" method, which reduces variability in the measurement (Dirks, Ahlstrom, and

Eisenberg 1996; Hawkins and Mueller 1986; Hawkins, Alvarez, and Houlihan 1991; Seewald 1991; Moodie, Seewald, and Sinclair 1994). Studies have shown highly repeatable test-retest reliability of this measure in children and adults (Sinclair et al., 1996) within even 1 dB of error (Munro & Davis, 2003). The probe-tube position was maintained during the ER-3A insert-earphone placement for the TFEC measurement (not pictured); the base of the insert-earphone was placed flush with the opening of the earcanal (not pictured).

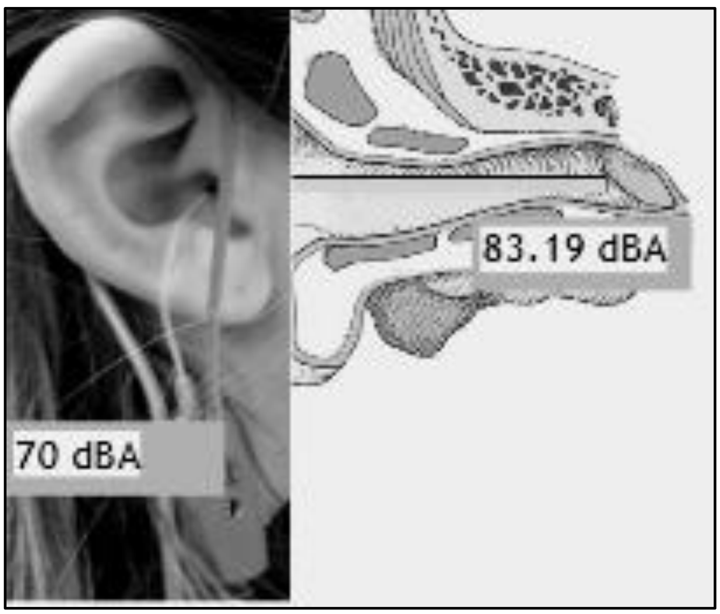

Figure 9.

TFOE measurement procedure: probe-tube was inserted into the unoccluded earcanal until the marker rested at the intertragal notch. The probe tube was marked such that it would consistently rest within 2-3 mm of the eardrum. The TFOE measurement is the difference between the sound-level measured at the reference-microphone outside the ear (in this case, 70 dB-A) and the sound-level measured at the probe tube near the eardrum (in this case, 83.19). In this figure, the example TFOE = 13.19 dB-A (83.19 - 70.00).

4.2.5 Stimuli Presentation and Measurement

The Audioscan Verifit 2 was calibrated for RECD measures and on-ear measures. Participants were situated 2 ft from the free-field speaker source (Verifit 2) per standard clinical protocol. The Verifit 2 automatically calibrates sound-level presentation for distance to participant by using a reference microphone near the participant's earlobe. The Verifit 2 on-ear probe-microphone system involves 2 microphones; a reference-microphone, which sits at the base of the ear and measures the free-field sound-level, and a probe-microphone which rests 2-3 mm from the eardrum in the earcanal and measures the inside-ear sound-level.

Open-ear probe-microphone measure (TFOE):

TFOE stands for "transfer function of the open ear"; it is the amount of amplification provided by all external-ear structures combined (pinna, concha bowl, earcanal). A probe-microphone measurement can be used to measure pink-noise stimulus inside an individual's unoccluded earcanal, and an FFT can be performed to measure sound levels within narrow frequency bands. The dB-SPL at individual frequencies within the FFT can then be transformed into dB-A measurements, from which overall dB-A can be derived; this reveals the amount of dB-A gain (amplification) that an individual receives from the anatomical properties of their combined external-ear structures (TFOE).

Occluded-ear probe microphone measure (TFEC):

TFEC stands for "transfer function of the earcanal"; it is the amount of amplification provided solely by the earcanal. The exact amount of earcanal amplification and attenuation of certain frequencies inside the resonator tube is unique to each individual, as these changes are a function of the earcanal size, angle, and length. TFEC can be used to map an FFT of a pink-noise stimulus inside an individual's occluded earcanal: the stimulus is presented through a ER-3A insert earbud sealed in the opening of the earcanal, and the stimulus level is measured 2-3 mm from the eardrum. The dB-SPL at individual frequencies can then be transformed into dB-A measurements, from which an overall dB-A can be calculated; this reveals the amount of amplification a person receives from the anatomical properties of their occluded earcanal.

Pink-noise Measurement #1 (TFOE):

In the first condition, the 60 dB-SPL stimulus was presented via the Verifit 2 free-field speaker and measured inside the open-ear with a probe-microphone. Under an A-weighted decibel scale - that which is used in measuring noise-dose and subsequent NIHL risk - this presentation stimulus is equivalent to a 58 dB-A sound-level.

Pink-noise Measurement #2 (TFEC):

In the second condition, a 55 dB-SPL pink-noise stimulus (sound-level measured inside a 2.0 cc coupler in 1/12 octave bands analysis) was presented in the occluded-ear, via an ER-3A insert earbud, and measured inside the occluded-ear with a probe-microphone. Under an A-weighted decibel scale - that which is used in measuring noise-dose - this stimulus is equivalent to a 53 dB-A sound-level. The extent to which the sound-level measured in the occluded-ear was different than the 53 dB-A measured in the coupler indicates the amount of external-ear amplification solely attributed to earcanal resonance.

4.2.6 Data Extraction and Noise-Dose Analysis

Verifit 2: Data was extracted via the "Export Session" Verifit 2 feature. An Excel spreadsheet template ("Audioscan Template"), provided by the manufacturer, extracts the Verifit's FFT for all measured stimuli in 12th octave steps from 200 - 12,500 Hz. It is important to note that the Audioscan Verifit 2 (and Verifit 1) system measure unweighted sound-levels (i.e., dB-SPL); however, when conducting a NIHL risk-assessment, sound-levels are required to be measured with an A-weighted filter applied such that OSHA and NIOSH tables can be used for noise-dose estimation purposes. As such, the sound levels at individual frequencies within the FFT were converted from dB-SPL to dB-A by applying the A-weighted correction factors listed in the OSHA Technical Manual (OSHA 1990). These correction factors are derived from the 40-phon equal-loudness contours of the Fletcher-Munson curves (Fletcher & Munson, 1933). Overall dB-A for each stimulus will be calculated as summed energy at 0.25, 0.5, 1, 2, 3, 4, 6, 8, 10, and 12.5 Hz (i.e., the subset of frequencies listed in the Verifit 2 summary table).

4.2.7 Pinna Size Measurement

Similar to preliminary data methods, pictures of the pinna were taken and measured for height (points A-B) and width (points C-D) using ImageJ computer software (Figure 2). Pinna height and width measurements were analyzed in ImageJ software. The software requires that the known measurements of an object is in view, so that it can calibrate other objects in the frame. A ruler was made visible in the frame to create this reference, and to cross-check measurements. Marker points were determined by the widest points on the ear both horizontally and vertically.

4.2.8 Experimental Flow

Participants (or their parents) were asked to give their informed consent (and informed assent, if applicable) to participate in the study. After informed consent was obtained, participants completed a survey regarding demographic information, then underwent unilateral otoscopy, tympanometry, and a photo of the pinna. Participants were then seated approximately 2 ft from the Verifit 2 speaker at ear-level, 0 degrees azimuth, to obtain external-ear amplification measurements, TFOE and TFEC.

First, participants underwent TFOE measurement. The reference-microphone was situated underneath the participant's earlobe, and the probe-tube was placed in the earcanal, per the procedures previously described. Steady-state pink-noise at 60 dB-SPL was recorded inside and outside the ear, and overall level was later analyzed after applying A-weighting to the dB-SPL measurements extracted during the FFT analysis.

Third, and lastly, participants underwent TFEC measurement. The probe-tube was placed in the earcanal, per the procedures previously described. A 53 dB-A pink-noise stimulus (as measured inside a 2.0 cc coupler) was presented via a ER-3A earbud was measured inside the ear, and later analyzed in a FFT after applying A-weighting to the dB-SPL measurements.

Participation in this research study involved one session which lasted approximately 10-15 minutes, in which the participant sat still and quietly while the previous list of clinical measurements of one ear were taken. All procedures are clinically standard, even for pediatric care. Each measurement was only taken once from one ear, as reliability between two different runs and right and left ears was determined to be high in the preliminary data.

4.3 Statistical Analyses

4.3.1 Power analysis

The overall goal was to estimate TFOE and TFEC using a single factor within a linear regression analysis model. It is understood that a multi-factor simultaneous regression model would likely yield a stronger correlation and R^2 value; however, the purpose of this experiment was to identify a single proxy metric which could easily stand-in for the complicated and technical probe-microphone measurement method. An a-priori power analysis based on preliminary data effect-size was conducted in G-power 3.1 software package, using single factor regression analyses. A sample size of <u>36 participants (18 male, 18 female) in each group (pediatric, teen, adult) was estimated in order to be powered for detection of a significant, medium effect size.</u> Preliminary data suggest a medium-large effect size (F^2 = .18 - .22) across statistically significant correlates (proxy metrics) of TFOE and TFEC. It was anticipated that effect size would increase in all models compared to the preliminary study, as the addition of a more diverse population would likely increase the range of values in the independent variables that estimate the TFOE and TFEC outcomes. The preliminary dataset was very homogenous (88% adult females), and so the variance in the preliminary dataset's predictors of anatomical body size and ear size - which have been shown to be related to age and sex – was very tight. This thesis involved gathering a new, heterogeneous dataset with more variable age (pediatric, adolescent, adult) and sex; these contributions were likely to strengthen the models, as external-ear size and subsequent amplification measurements were likely to widen as a function of both age and sex.

4.3.2 TFOE and TFEC Age Group and Sex Differences

Outcome variables (TFOE and TFEC) were normally distributed; TFOE and TFEC within age-groups (pediatric, adolescent, adult) passed a Homogeneity of Variance test using both the group mean and group median. Two-way ANOVA was conducted to assess main effects of sex and age group on TFOE and TFEC. When necessary, a Tukey post-hoc test was used to identify which groups were different from one another.

4.3.3 Estimating TFOE and TFEC Using Proxy Metrics

Several single-predictor linear regression models were generated to test statistical significance of proxy metrics of TFOE and TFEC. TFOE linear regression models included the following factors, each in their own, single-predictor model: TFEC, height, earcanal volume, eardrum compliance, pinna width, pinna height. TFEC models included the following factors, each in their own, single-predictor model: TFOE, height, earcanal volume, eardrum compliance.

4.3.4 Outliers

Participants with negative middle ear pressure exceeding -200 daPa were excluded from all analyses; clinicians commonly regard this degree of negative pressure as significant for middle ear dysfunction (potentially influential in measuring earcanal volume and tympanic membrane compliance), and were thus excluded from analyses.

No TFEC outliers were observed outside 2 standard deviations of the mean; no TFEC data were excluded.

TFOE outliers were observed, defined as exceeding 3 standard deviations below the mean. Low amplification outliers were excluded from analyses (TFOE < 5 dB-A); these excessively low amplification TFOE values were presumed to be a function of probe microphone movement slipping out of the earcanal, likely associated with incidental participant head movement during testing. TFOE outliers above the mean were not excluded, as they are biologically plausible, and are unlikely to be erroneous.

4.4 Results

4.4.1 TFOE Age Group and Sex Differences

Across all participants, age 4-8, 13-17, and 18+ years, mean TFOE was 10.9 dB-A (range 5 - 19 dB-A). No main effect of sex was observed for TFOE ($p = .51$) (Figure 10); however, a main effect of age group was observed for TFOE. Adult and adolescent groups did not show a statistically significant difference in TFOE from one another ($p = .07$); however, pediatric group TFOE showed a statistically significant difference compared to the adult and adolescent groups ($p = .04$, $p = .01$, respectively) (Table 8) (Figure 11). Subsequent TFOE regression analyses were performed on two groups: 1) a combined adult+adolescent TFOE group, and 2) a pediatric TFOE group.

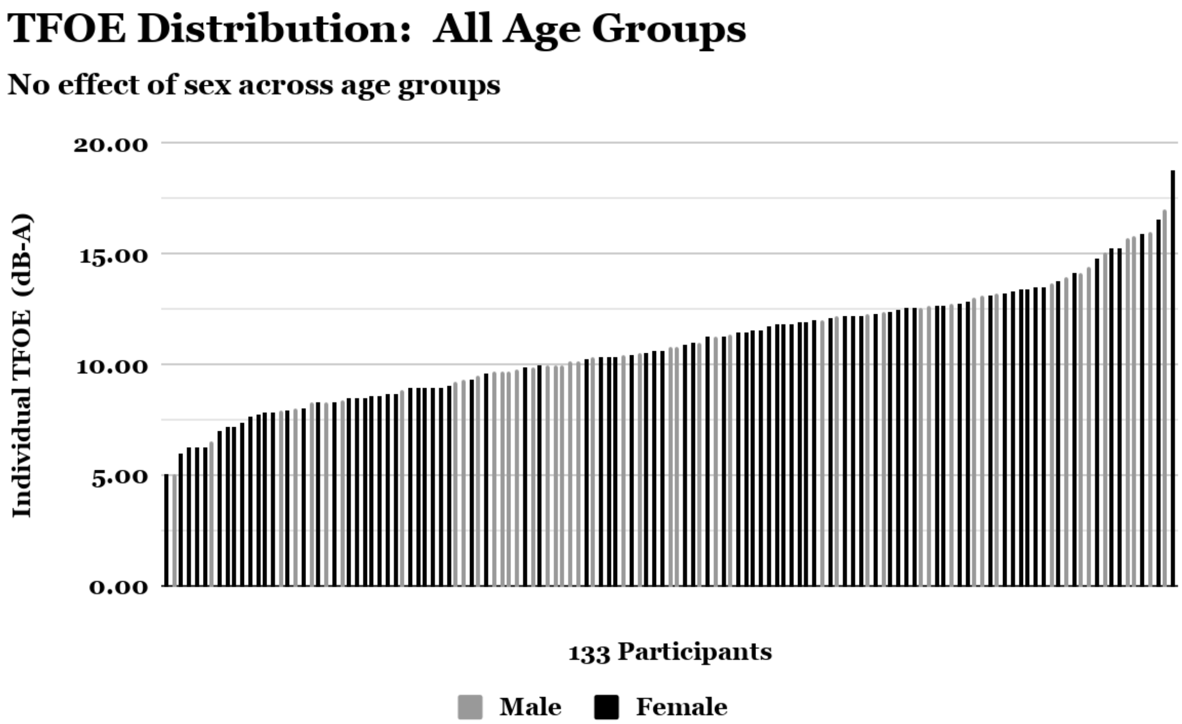

Figure 10.

Across participants from all age groups, TFOE ranged from 5 - 19 dB-A (mean 10.9 dB-A).

Table 8.

Across age groups, only pediatric TFOE was statistically different than adult TFOE (p =.04).

ANOVA Post-Hoc Results - TFOE Differs Across Some Age Groups

	Adult	Adolescent	Pediatric
Adult	x	x	x
Adolescent	p=.07	x	x
Pediatric	**p= .04**	**p=.01**	x

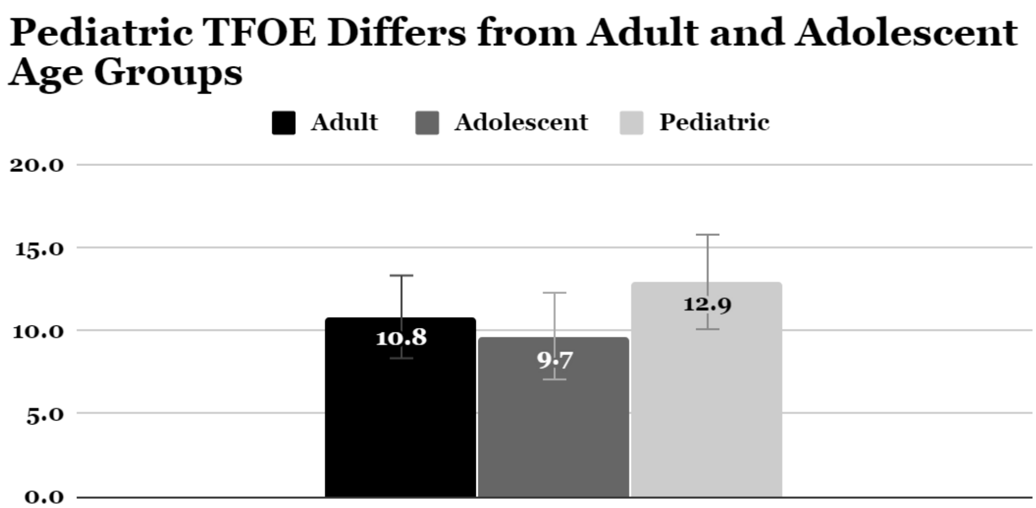

Figure 11.

While adult and adolescent TFOE did not statistically differ from one another (p = .07), pediatric TFOE statistically differed from both adult and adolescent TFOE (p = .001); on average, pediatric TFOE was higher than adult and adolescent TFOE.

4.4.2 TFEC Age Group and Sex Differences

Across all participants, age 4-7, 13-17, and 18+ years, mean TFEC was 14.6 dB-A (range 8-19 dB-A). Statistically significant differences in TFEC were observed between some age groups, and an effect of sex was detected across all age groups, and within some age groups. Adult and adolescent group TFEC did not statistically differ (p = .69); however, pediatric TFEC was statistically different than adult TFEC (p = .02) (Table 9) (Figure13); distribution across all participant's TFEC is shown in Figure 12. Across all age groups, a main effect of sex was observed (p = .001), with females exhibiting higher TFEC than males. Within age groups, the effect of sex on TFEC was only present in the adult age group (Table 10) (Figure 14); female adult participants exhibited higher TFEC than male adult participants (p = .01). Subsequent TFEC regression analyses were performed on two groups: 1) a combined adult+adolescent TFEC group, and 2) a pediatric TFEC group.

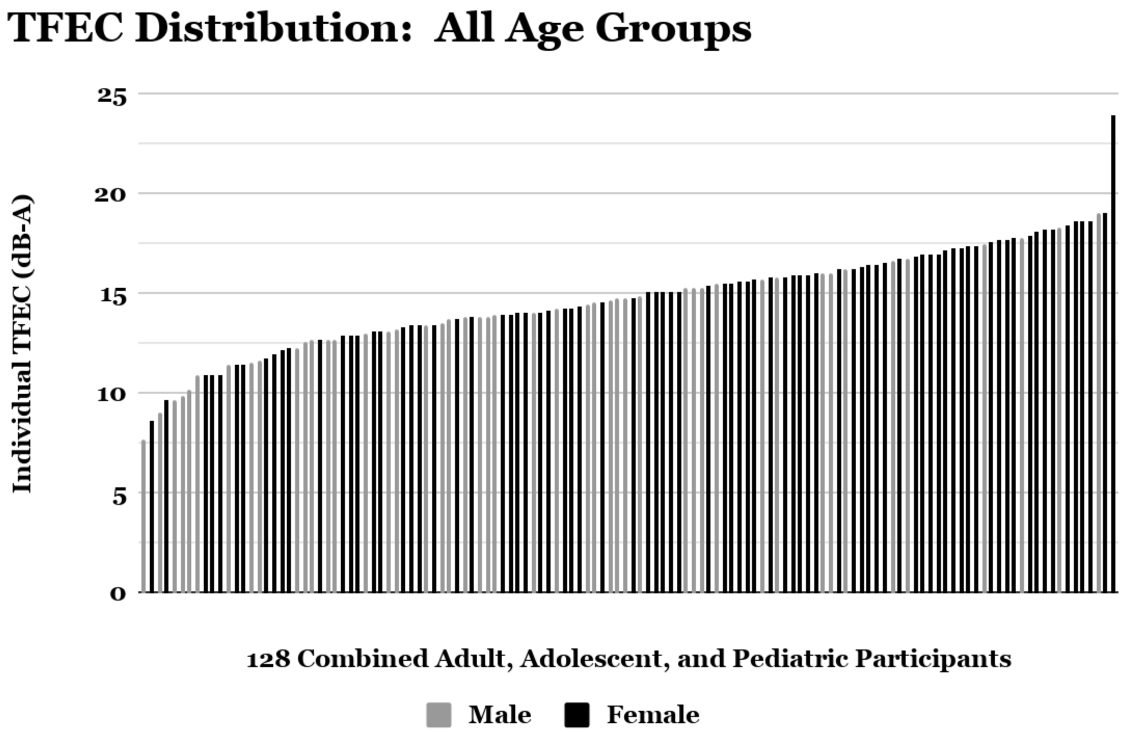

Figure 12.

Participant's TFEC distribution is shown here. TFEC ranged 8-19 dB-A (mean = 14.6 dB-A). TFEC statistically differed between the pediatric and adult age groups.

Table 9.

Across age groups, only pediatric TFEC was statistically different than the adult TFEC (*p* =.02).

ANOVA Post-Hoc Results - TFEC Differs Across Some Age Groups

	Adult	Adolescent	Pediatric
Adult	x	x	x
Adolescent	p=.69	x	x
Pediatric	$\boldsymbol{p}$**= .02**	p=.28	x

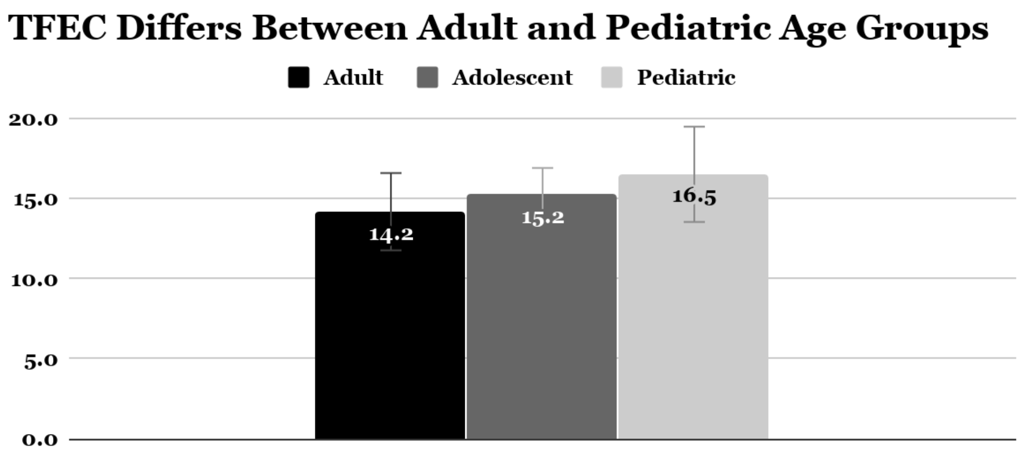

Figure 13.

Pediatric TFEC was reliably higher than adult TFEC (p = .02).

Table 10.

TFEC was statistically different as a function of sex across age groups (p =.001). Within age groups, the effect of sex on TFEC was only observed in the adult age group; adult males exhibited lower TFEC than adult females (p =.01).

ANOVA Post-Hoc Tukey Results - TFEC Differs by Sex within Adult Age Group Only

	Adult female	Adult male	Adol. female	Adol. male	Ped. female	Ped. male
Adult female	x	x	x	x	x	x
Adult Male	***p*=.01**	x	x	x	x	x
Adol. female	*p*>.05	*p*>.05	x	x	x	x
Adol. male	*p*>.05	*p*>.05	*p*>.05	x	x	x
Ped. female	*p*>.05	*p*>.05	*p*>.05	*p*>.05	x	x
Ped. male	*p*>.05	*p*>.05	*p*>.05	*p*>.05	*p*>.05	x

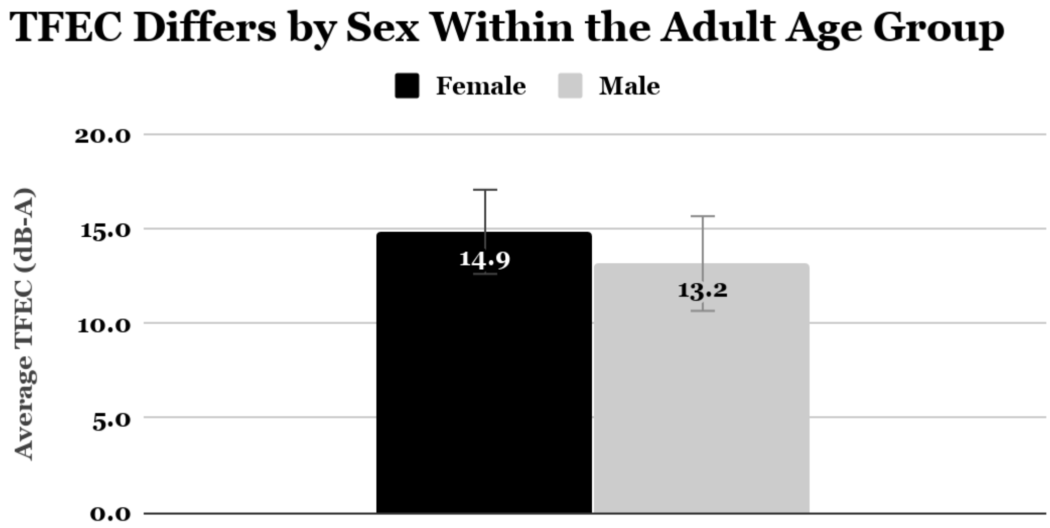

Figure 14.

TFEC differs as a main effect of sex (*p* =.001); post-hoc analysis revealed the difference within solely the adult age group (*p* =.01). On average, adult males have lower TFEC than adult females.

In summary, TFOE varies 5-19 dB-A, and TFEC varies 8 -19 dB-A across participants. A main effect of age group is observed in both TFOE and TFEC; the pediatric age group exhibited higher TFOE and TFEC than the adolescent and adult group (p <.05). A main effect of sex was not observed in TFOE, but was observed in TFEC; a post-hoc Tukey test showed adult female TFEC to be significantly higher on average than adult male TFEC (p < .05).

4.4.3 Viable Proxy Metrics for TFOE: Adult+Adolescent Age Group (13+years)

4.4.3a Pinna Height Estimates TFOE

Adult+adolescent TFOE can be estimated with statistical significance (p = .01) using the single proxy metric of pinna height (in) and the linear regression model y = 1.057x + 4.591 (Figure 15). This model estimates 84% of TFOE within 3 dB-A of the participant's true TFOE. As such, amplification derived from the size of the pinna may drive TFOE variability; as pinna height increases, TFOE increases. This relationship shows a moderate correlation with a small effect size (R=.28, R^2 = .08, F^2 = .09), detected with sufficient power of .90. Essentially, the pinna serves as a funnel for amplification, and the larger the funnel, the more sound is captured. Though male and female pinna height statistically differ in the adult+adolescent group (p < .01), TFOE does not statistically differ by sex as a main effect (p > .05). Regarding the effect of sex, the take home message may be that, although males tend to have larger pinnae, this is not the case often enough to create statistically significant differences in TFOE as a function of sex. Another take-home message may be that, although male pinnae tend to be larger than female pinnae (raising amplification), male earcanals also tend to be larger than female earcanals (lowering amplification), and so the effect of sex may be washed out.

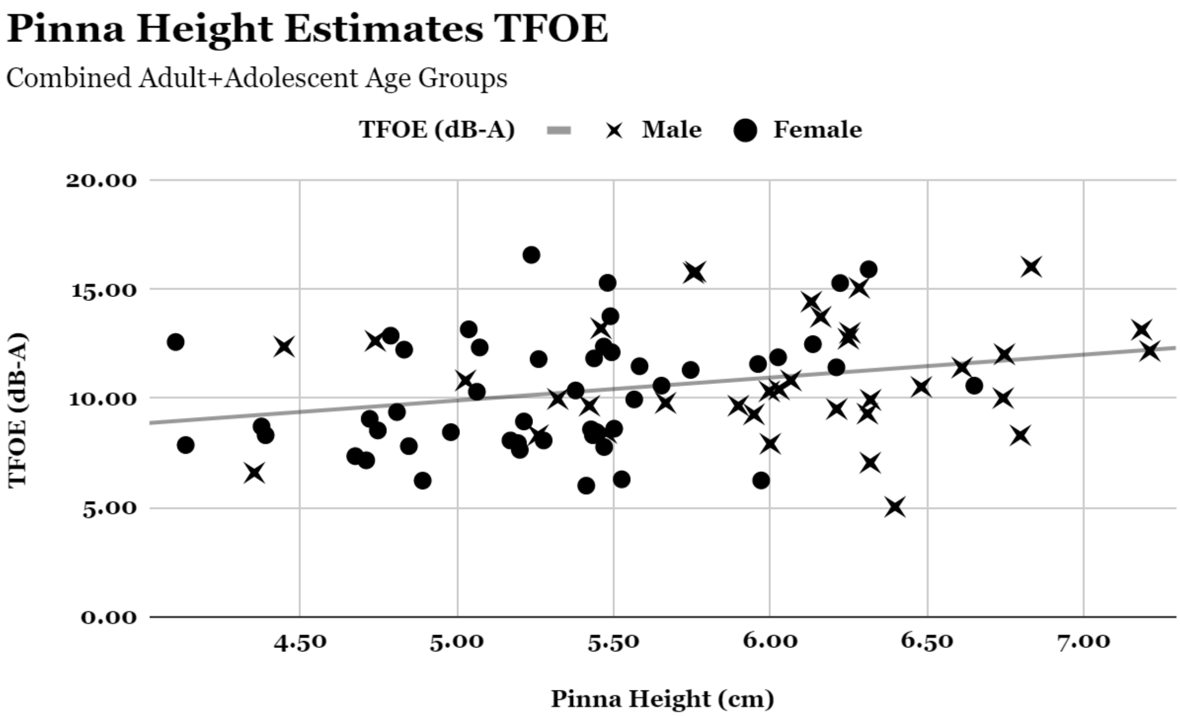

Figure 15.

In the adult+adolescent group, pinna height (cm) was significantly correlated with TFOE (p = .01).

4.4.3b TFEC Estimates TFOE

Adult+adolescent TFOE can also be estimated by the proxy metric of TFEC within the linear regression model y = .315x+6.127 (Figure 16) (p = .001). This model estimates 84% of TFEC within 3 dB-A of the participant's true TFOE. Amplification from the earcanal component of the external ear (TFEC) is correlated with amplification of the entire external ear (TFOE); as TFEC increases, TFOE increases. This relationship has a moderate correlation with a small effect size (R=.30, R^2 = .09, F^2 = .10), detected with sufficient power of .92.

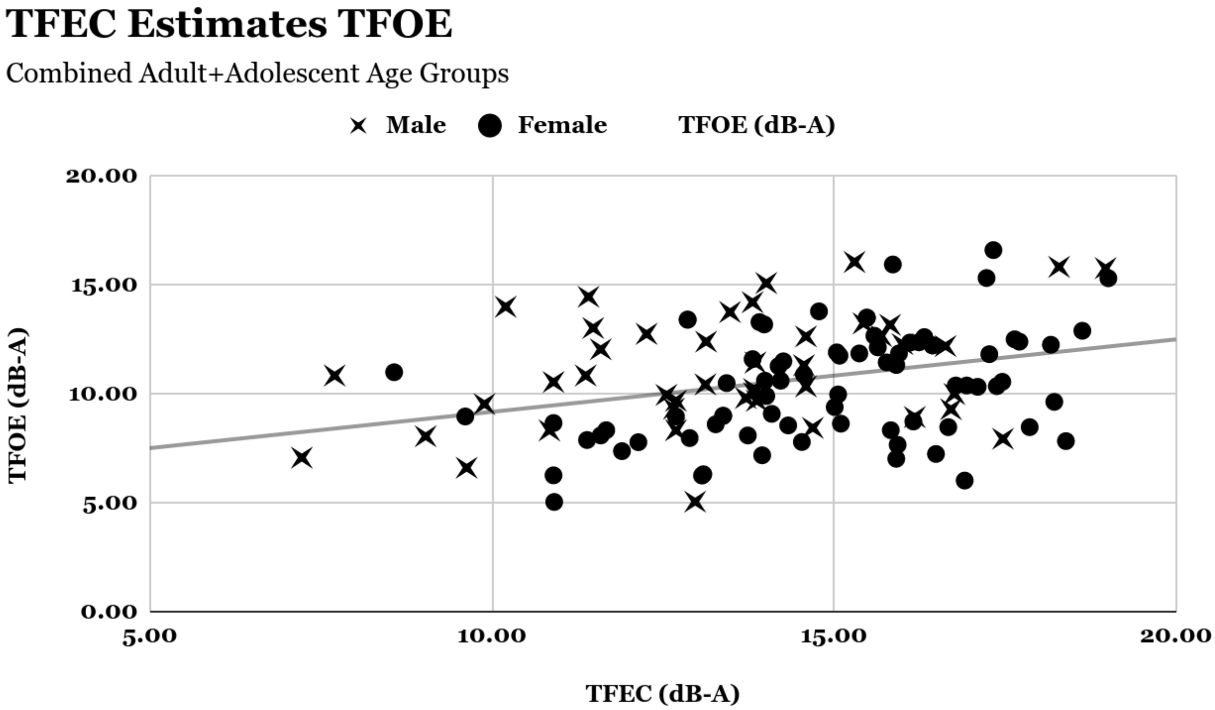

Figure 16.

In the adult+adolescent age group, TFEC significantly estimates TFOE (p = .001).

4.4.4 Non-Viable Proxy Metrics for TFOE & TFEC

In the adult+adolescent group, TFOE was not reliably correlated with the following proxy metrics with statistical significance: body height, earcanal volume, eardrum compliance, pinna width (Table 11). In the adult+adolescent group, TFEC was not tested for proxy metrics other than body height and earcanal volume (with which it was reliably correlated, see 4.4.5), as no other proxy metrics were viewed as theoretically grounded.

Table 11.

Depicted in this table are the relationships observed in various linear-regression models attempting to estimate TFOE and TFEC. Relationships that signify statistically significant proxy metrics of TFOE and TFEC are bolded.

Linear Regression Results - Summary Proxy Models of TFOE and TFEC

	TFOE (dB-A)	TFEC (dB-A)
TFOE (dB-A)	x	x
TFEC (dB-A)	**p<.01**	x
Height (in)	p=.63	**p<.01**
Earcanal Volume (cc)	p=.35	**p<.01**
Tympanic Membrane Compliance (ml)	p=.37	x
Pinna width (in)	p=.18	x
Pinna height (in)	**p=.01**	x

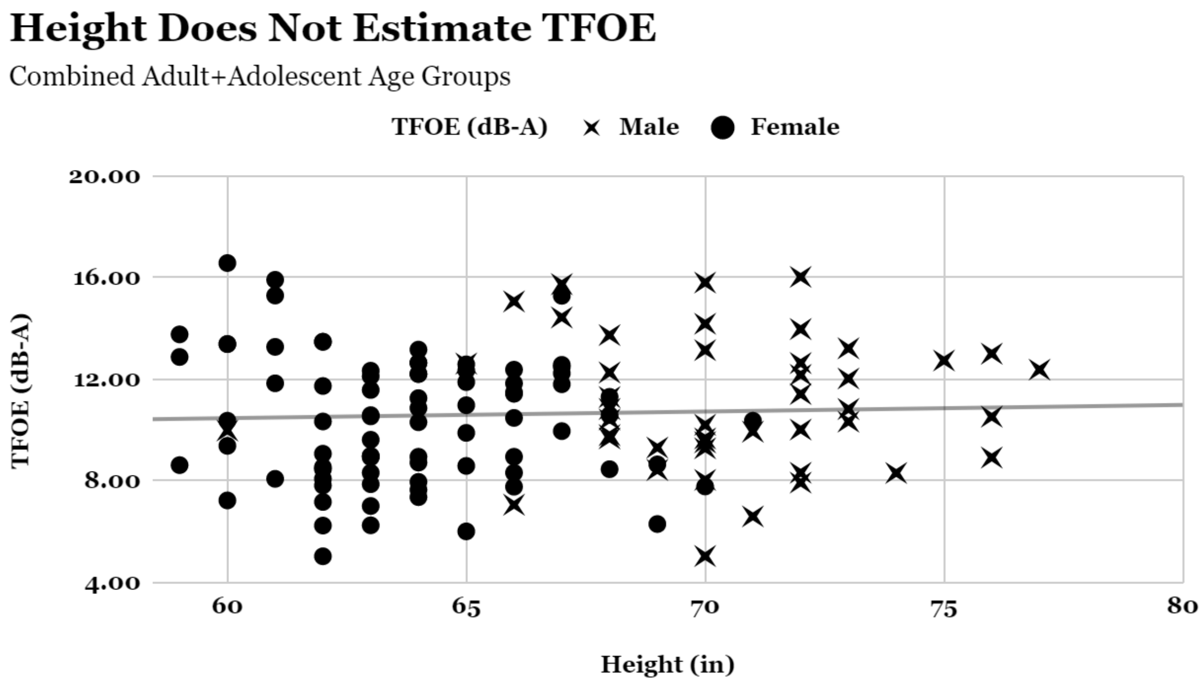

Figure 17.

No correlation was observed between body height and TFOE (R=.002) (p = .63).

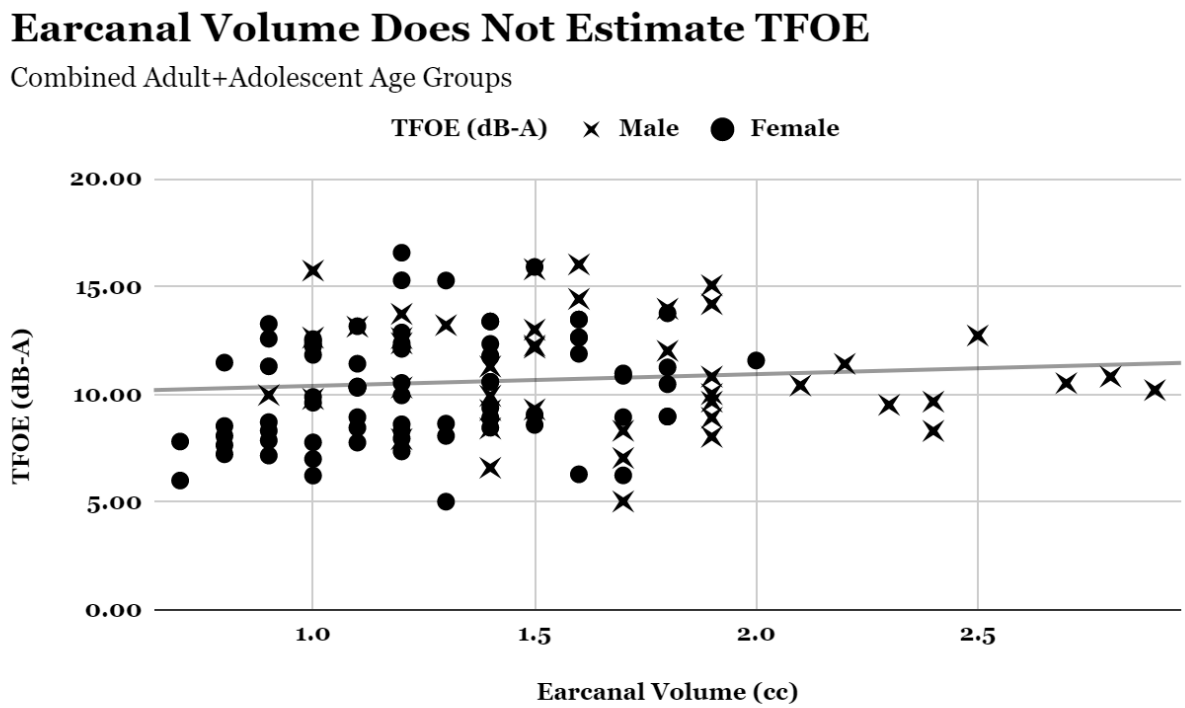

Figure 18.

The relationship between earcanal volume and TFOE was a weak correlation (R=.01), and was not statistically significant (p = .35).

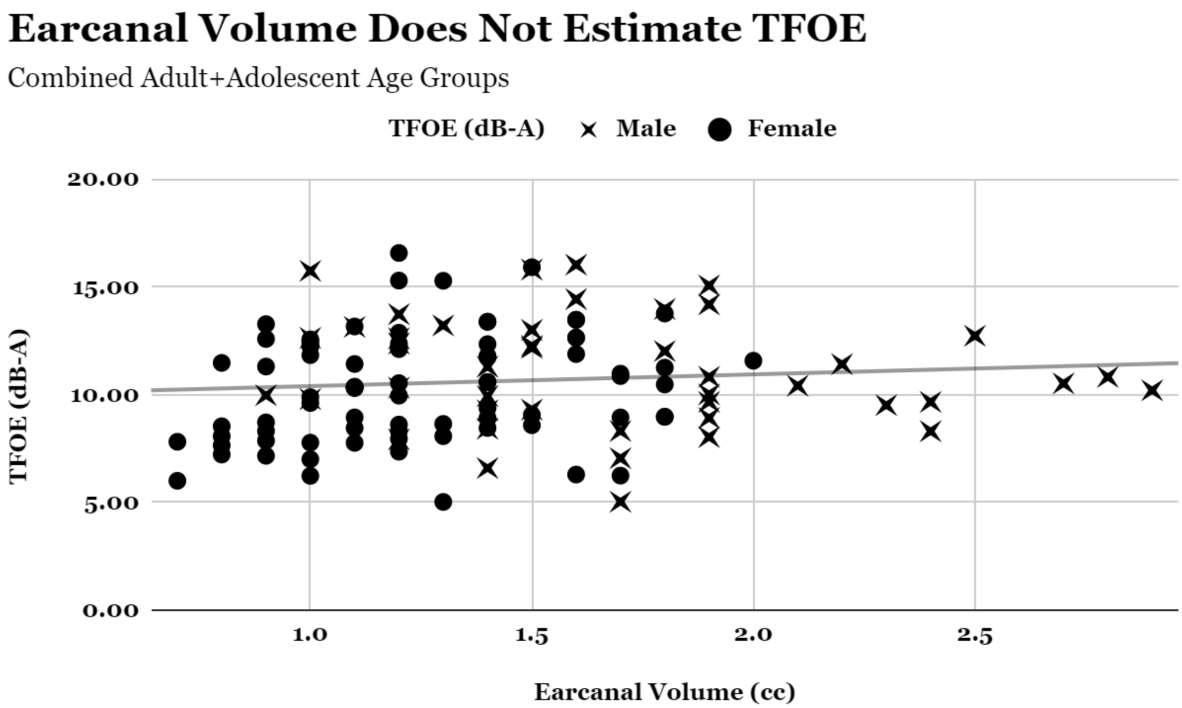

Figure 19.

The relationship between eardrum compliance and TFOE was a weak correlation (R=.01), and was not statistically significant (p = .37).

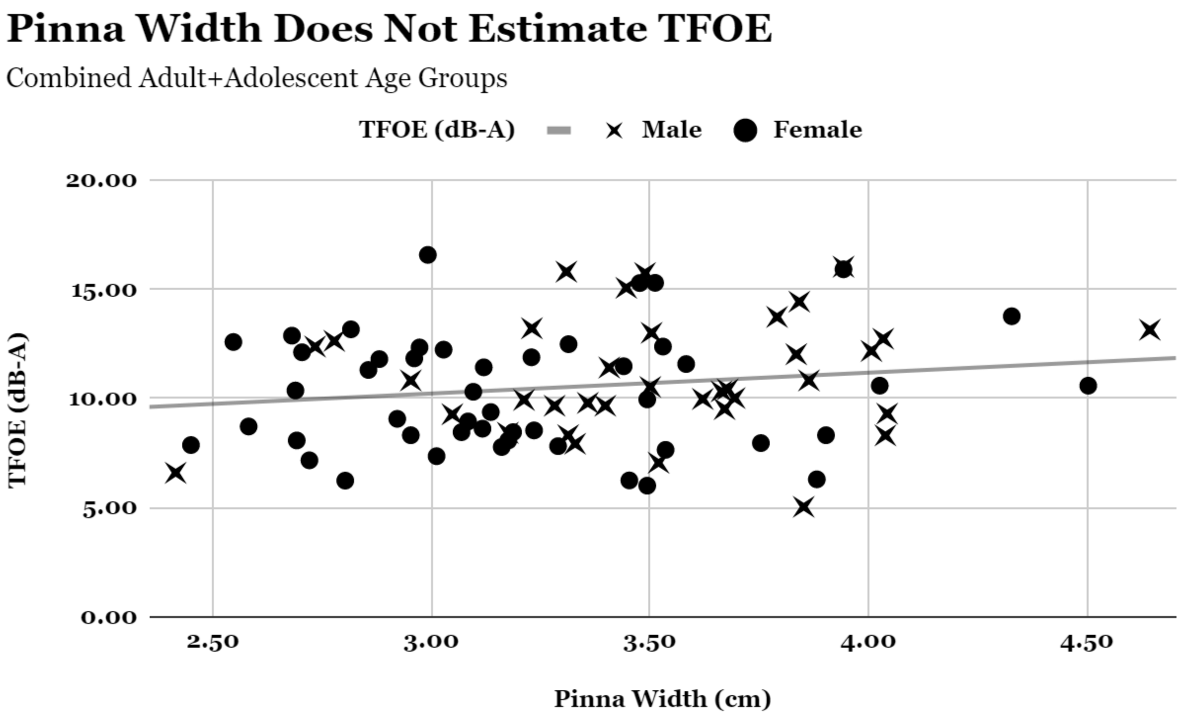

Figure 20.

The relationship between pinna width and TFOE was a weak correlation (R=.02), and was not statistically significant (p = .18).

4.4.5 Viable Proxy Metrics for TFEC: Adult+Adolescent Age Group

4.4.5a Earcanal Volume Estimates TFEC

Adult+adolescent TFEC can be estimated with statistical significance ($p < .01$) using the single proxy metric of earcanal volume (cc) and the linear regression model y = -2.62x + 18.072 (Figure 21). This model estimates 92% of TFEC within 3 dB-A of the participant's true TFEC. As such, the volume (size) of the resonator cavity (earcanal) may drive the amount of TFEC amplification; as earcanal volume increases, TFEC decreases. This relationship has a strong correlation with a medium effect size (R=.49, R^2 = .24, F^2 = .27), detected with sufficient power of .92. Male and female earcanal volume and TFEC differed with statistical significance (p <.05) in the adult+adolescent group; males exhibited larger average earcanal volumes and lower average TFEC than females.

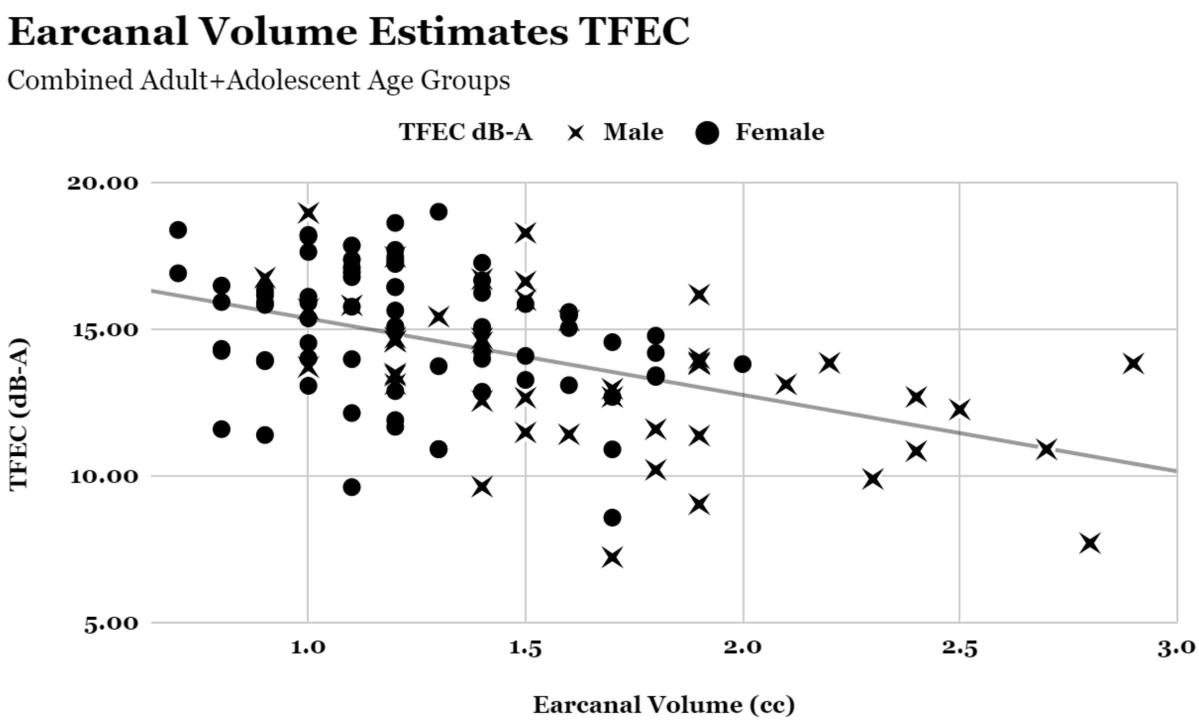

Figure 21.

Earcanal volume (cc) served as a reliable proxy metric for individual TFEC (p<.01); as earcanal volume increases, TFEC decreases.

4.4.5b Height Estimates Earcanal Volume

Adult+adolescent earcanal volume can be estimated with statistical significance (p < .01) using the single proxy metric of body height within the linear regression model y = .042x – 1.389

(Figure 22). On average, as body height increases, earcanal volume (cc) increases. This relationship has a strong correlation with a medium effect size (R=.51, $R^2 = .26$, $F^2 = .27$), detected with sufficient power of .92.

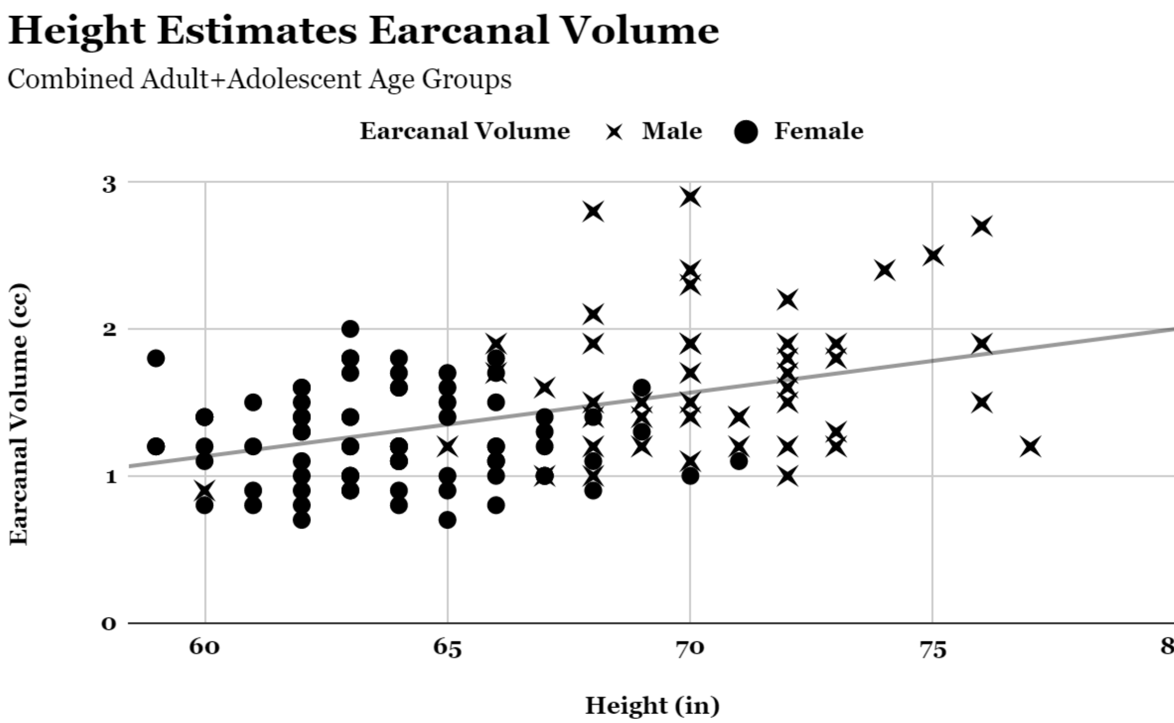

Figure 22.

In the adult+adolescent group, body height (in) was reliably correlated with earcanal volume (cc) (p <.01). Both body height and earcanal volume differed as a function of sex in the adult+adolescent group (p < .05); males were taller and had larger earcanal volumes.

4.4.5c Height Estimates TFEC

Adult+adolescent TFEC can be estimated with statistical significance (p < .01) using the single proxy metric of body height (in) and the linear regression model y = -.149x + 24.259 (Figure 23). This model estimates 88% of TFEC within 3 dB-A of the participant's true TFEC. As previously shown in Figure 22, the volume (size) of the earcanal is related to the individual's height (a measure of general body size), and Figure 21 shows earcanal size to be related to TFEC; as such, the relationship shown in Figure 23 is a logical step: as height increases, TFEC decreases. This relationship has a moderate correlation with a small effect size (R=.30, R^2 = .07, F^2 = .08), detected with sufficient power of .86. Male and female height and TFEC differ with statistical significance in the adult+adolescent group (*p* <.05); on average, males were taller and had lower TFEC in the adult+adolescent age group.

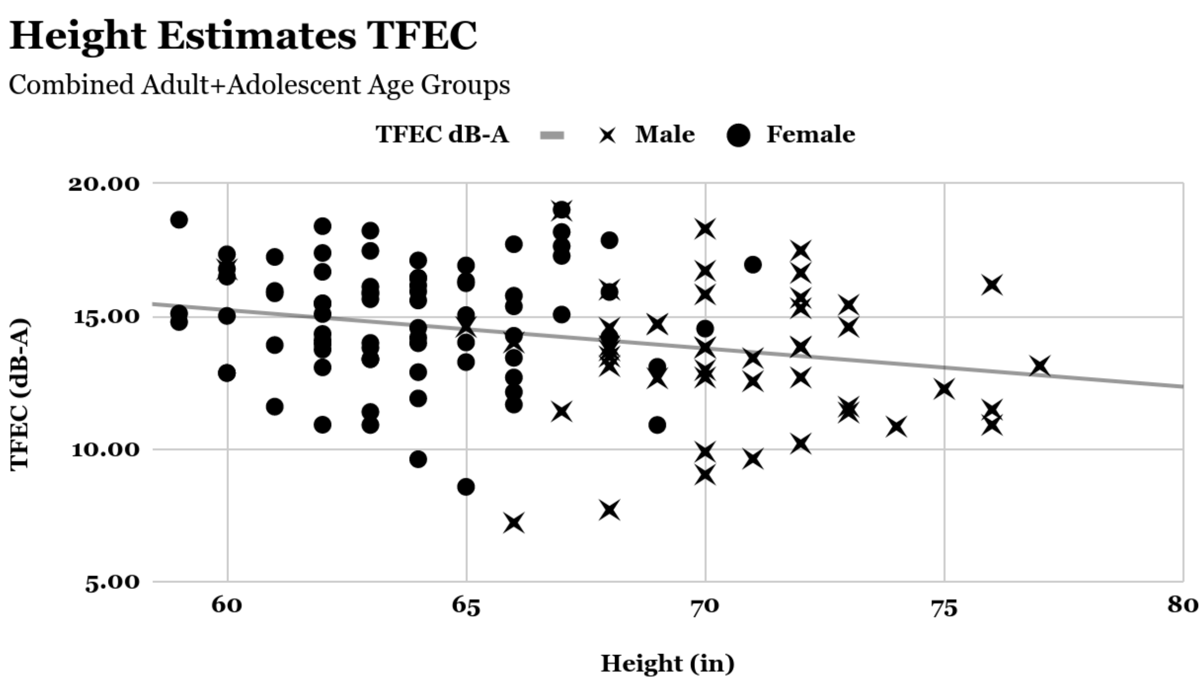

Figure 23.

In the adult+adolescent group, height (in) was reliably correlated with TFEC (*p* <.01). Both height and TFEC differed as a function of sex in this adult+adolescent group (*p* < .05); on average, males were taller and had lower TFEC in the adult+adolescent age group.

4.4.6 TFOE Proxy Correlation: Pediatric Group

4.4.6a Pinna Height and TFOE Correlation

Pinna height is not correlated with TFOE in the pediatric group, as compared to the correlation among the adult+adolescent group (R = .12, R^2 = .01, p =.77). A very small effect size was observed for pinna height on the influence of TFOE within the pediatric group; this group appears to be too variable in pinnae and earcanal measurements to reliably apply the adult+adolescent model, or to create a new model within the age group.

4.4.6b TFEC and TFOE Correlation: Pediatric Group

Similar to the adult+adolescent group, TFEC is highly correlated with TFOE in the pediatric group, as seen in the adult+adolescent group, though it is not statistically significant (R = .44, R^2 = .19, p =.12). Again, although the correlation is present, there is likely too much variability in the pediatric population to render statistical significance.

4.4.7 TFEC Proxy Correlation: Pediatric Group

4.4.7a Earcanal Volume Estimates TFEC

Similar to the adult+adolescent group, TFEC is highly correlated with earcanal volume in the pediatric group, as seen in the adult+adolescent group, though not statistically significant (R= .44, R^2 = .12, p =.12). Again, although the correlation is present, there is likely too much variability in the pediatric population to render statistical significance.

4.4.7b Height Estimates TFEC

Similar to the adult+adolescent group, height is highly correlated with TFEC in the pediatric group, as compared to the correlation in the adult+adolescent group, though not statistically significant (R = .44, R^2 = .12, p =.12). Again, although the correlation is present, there is likely too much variability in the pediatric population to render statistical significance.

In summary, both TFOE and TFEC are highly variable across participants. Pediatric TFOE and TFEC statistically differs from adolescent and adult TFOE and TFEC, with the pediatric population exhibiting more external-ear amplification on average. A main effect of sex is not observed in TFOE, but is observed in TFEC; a post-hoc Tukey test revealed that females exhibit more external-ear amplification than males within the adult age group. Within the adult + adolescent age group, TFOE can be estimated using the proxy metric of pinna height, and TFEC can be estimated using the proxy metric of earcanal volume or body height; these correlations are statistically significant ($p < .05$). Within the pediatric group, similar correlations between proxy metrics and TFOE and TFEC were observed; however, these correlations were not statistically significant ($p > .05$), and thus, estimating TFOE and TFEC using proxy metrics and linear regression was not feasible.

4.5 Testing the Model

The adult + adolescent regression models for estimating TFOE, TFEC, and earcanal volume generated from the secondary dataset were tested on the preliminary dataset of 48 adult participants (18+ years). When tested on the preliminary dataset, the linear regression equations maintained high accuracy in estimating TFOE, TFEC (Table 12), and earcanal volume (Table 13).

Table 12.

The proxy metrics which modeled TFOE, TFEC, and earcanal volume in the secondary dataset also reliably estimate these outcomes in the preliminary dataset of 48 adult participants (18+ years).

Linear Regression Results - Testing TFOE and TFEC Models in the Pilot Dataset

Proxy Metric	Equation	% within 3-dB: 158 participant model	% within 3-dB: 48 participant model
Pinna height estimates TFOE	y = 1.057x + 4.591	84%	92%
TFEC estimates TFOE	y = .315x + 6.127	84%	88%
Earcanal volume estimates TFEC	y = -2.62x + 18.072	92%	100%
Height estimates TFEC	y= .149x + 24.259	88%	94%

Table 13.

The statistically significant and strong correlation between height and earcanal volume in the secondary dataset was also reliably observed when tested in the preliminary dataset of 48 adult participants (18+ years).

Linear Regression Results - Testing Earcanal Volume Model in a New Dataset

Proxy Metric	Equation	Correlation: 158 participant model	Correlation: 48 participant model
Height estimates earcanal volume	y = .042x - 1.389	R= .51	R= .44

The linear regression models that reliably estimated outcome variables TFOE, and TFEC in the adult + adolescent age group (158 participants) using proxy anatomical measurements were equally successful in estimating TFOE and TFEC when applied to the preliminary dataset (48 participants). Separately, the strong and statistically significant regression model which estimated earcanal volume using body height in the adult + adolescent age group (158 participants) was also statistically significant when applied to the preliminary dataset (48 participants).

CHAPTER 5

DISCUSSION

5.1 Summary

The current study examined external-ear amplification as a possible source of individual variability that may help explain why some individuals are more susceptible to NIHL than others. This cross-sectional study examined variance in the individual transfer function of the open ear (TFOE) (i.e., external-ear amplification from the combined pinna, concha bowl, and earcanal structures) and the individual transfer function of the earcanal (TFEC) (i.e., external-ear amplification solely from the earcanal structure) across 158 participants.

The first goal of the study was to document the variability of individual TFOE and TFEC in a heterogeneous dataset, as greater external-ear amplification could contribute to greater individual NIHL-risk. TFOE range was 5-19 dB-A with a mean of 10.6 dB-A - these results are similar to the 9.8 dB-A TFOE mean reported by Shotland, 1996. TFEC variability in this study was 8-19 dB-A with a mean of 15 dB-A.

The second goal of this study was to identify proxy metrics of TFOE and TFEC, as the probe-microphone measurements used to obtain these measurements directly are cumbersome, invasive, and require technical training and equipment. TFOE was reliably estimated by proxy metrics pinna height and TFEC. Pinna height is the more practical proxy metric of TFOE, as this measurement simply requires a ruler, and it is not nearly as complex to perform as TFEC, which requires the same amount of work and technical skill as the TFOE measurement itself. It is likely that pinna height estimates TFOE because it serves as a funnel and amplifier for sound; it seems that the larger the funnel, the higher the sound-level. TFEC was reliably estimated by proxy metrics earcanal volume and body height; it seems that the larger the body, the larger the earcanal. For feasibility and simplicity, body height is the preferred proxy metric of the two, though for accuracy, earcanal volume exhibited the stronger correlation.

5.2 Dissertation Proposal Hypotheses Tested

1) **S**ignificant group differences will reveal higher TFOE in adult females than adult males, irrespective of age.
    a) Result: Data did not support this hypothesis. There was no effect of sex on TFOE across or within age groups. Driving external-ear amplification is the size of the structures of the external-ear, which are generally correlated with height; while females tend to be smaller than males, this is not always the case.
2) Adolescent male and female TFOE measurements will not significantly differ from adult male and female TFOE measurements.
    a) Result: Data supported this hypothesis. There were no statistically significant differences in adolescent to adult TFOE comparisons within sex; groups were combined for subsequent analyses. The lack of differences suggests that TFOE is fairly stable by age adolescence.
3) TFOE will be higher in the pediatric group, irrespective of sex, than the adult and female adult and adolescent groups.
    a) Result: Data supported this hypothesis. Pediatric TFOE is significantly higher than the adult+adolescent TFOE, regardless of sex. Pediatric pinna height and earcanal volume (cc) are also smaller than the adult+adolescent group (p<.05).
4) Eardrum compliance and TFEC will each separately estimate 95% of individual TFOEs accurately within 5 dB-A.

a) Result: Data did not support this hypothesis. Unlike the relationship observed in the preliminary dataset, eardrum compliance did not reliably estimate TFOE in the final dataset. The failure of this hypothesis in a larger, heterogeneous dataset is presumably a function of the preliminary dataset being a mostly female, homogeneous dataset, with little variance in external-ear structures. Instead, pinna height drove TFOE, and it estimates 95% of individual TFOE accurately within 5 dB-A, and even 84% within 3 dB-A.
b) Result: Data supported this hypothesis. TFEC reliably estimated TFOE within 5 dB-A; as seen in the preliminary dataset, TFEC and TFOE were highly correlated throughout. This proxy metric is of limited use, as the procedure to obtain TFEC as a proxy for TFOE is equally complex as obtaining TFOE directly.

5.3 Individual NIHL-risk Scenarios

Inability to predict individual susceptibility to NIHL has been one of the field's challenges in reaching a consensus about NIHL-risk criteria for the general population, both occupationally and recreationally. On the one hand, extremely restrictive noise limit regulations could be implemented so that even the most vulnerable populations would be protected from NIHL; prevention of occupational NIHL would have significant economic benefits (Neitzel, Richard L., et al. 2017). On the other hand, if noise-limit regulations were so restrictive that they protected even the most at-risk individuals from NIHL, the industry cost of compliance and the government cost of enforcement would be prohibitive. Realization of these difficulties, associated with the suggestion of completely preventing NIHL in even the most vulnerable individuals, resulted in significant lobbying of the U.S. Congress to set less restrictive noise-limits, knowing that some subset of individuals would, indeed, develop hearing loss while in full compliance with regulations (for detailed discussion see Neitzel et al. 2017). This thesis seeks a strategy to identify this most vulnerable subset of individuals, and suggests that those at highest risk of NIHL could be those with the largest TFOE and largest TFEC values. The data from this thesis suggest that simple proxy metrics of TFOE (pinna height) and TFEC (body height, earcanal volume) could reliably estimate these measurements of external-ear amplification.

Neither the current 29 CFR 1910.95 (1983) noise regulations nor the scientific guidance provided by NIOSH (1998) take individual external-ear amplification into consideration when calculating noise-dose and NIHL risk. Next in this discussion, several hypothetical scenarios will illustrate the magnitude of variable external-ear amplification effect on individual in-ear noise-dose and subsequent NIHL-risk assessment.

5.3.1 Scenario 1: Individual Noise-Dose at a Live Music Concert

The first hypothetical scenario is a live concert-music exposure, in which all of the participants (all age groups) hypothetically attend an identical 2 hour 100 dB-A live music concert and obtain an identical noise-dose (that is, if all participants were arranged such that the concert sound-level was 100 dB-A at each of their ears). In this scenario, every participant would accumulate a 100% noise-dose during the concert (black bars, Figure 24) using conventional sound-level meter or dosimeter measurement techniques. Equal noise-dose would imply equal-risk among all participants; however, ISO noise-induced hearing loss estimates clearly show that this is not the case. Keeping in mind that the current set of participants had TFOE amplitudes ranging from 5 - 19 dB-A, their in-ear exposure sound-levels (near the eardrum) are actually estimated to range from 105 - 119 dB-A at this hypothetical concert. If the individual in-ear noise-doses were estimated for each participant including the consideration of total external-ear amplification, noise-doses across the participants would range from 200% (2 hours x 105 dB-A) to 1,429% (2 hours x 119 dB-A) (grey bars, Figure 24). Based on these estimated noise-dose data, the participant with the highest TFOE would accrue 7x the in-ear noise dose as the participant with the lowest TFOE during this music concert exposure.

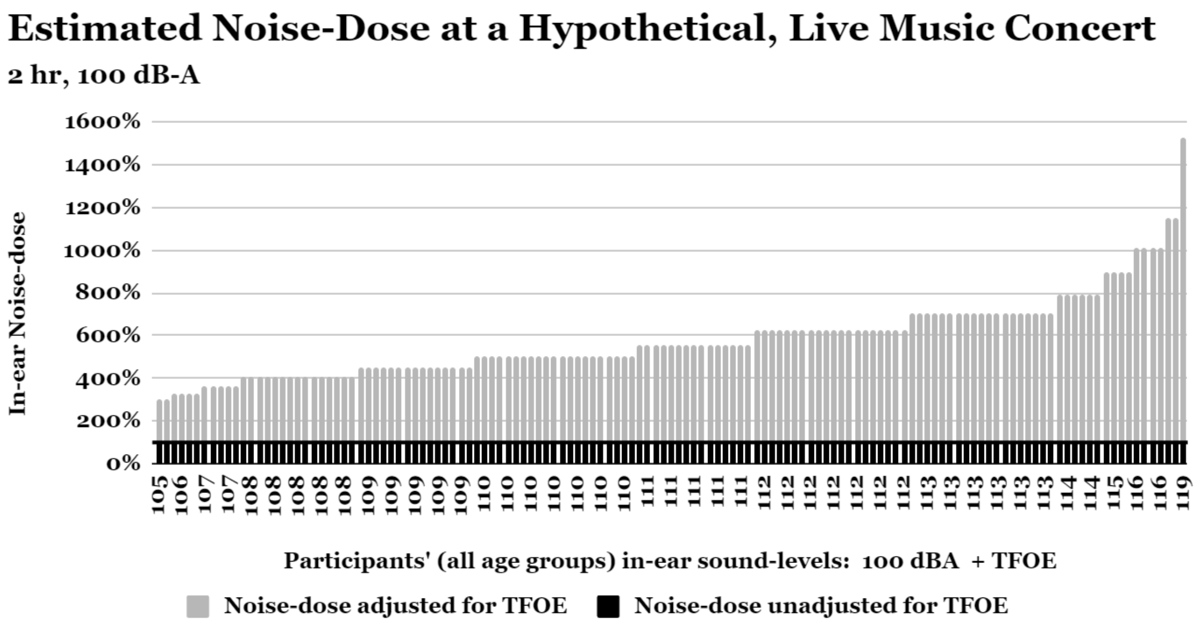

Figure 24.

In a hypothetical, 2 hour music concert exposure of 100 dB-A, the participant's individual in-ear noise-doses are extrapolated with and without consideration of their individual TFOE. Without consideration of individual TFOE, every participant would accumulate 100% noise-dose, based on sound-level measurements obtained outside the ear. With consideration of individual TFOE, participant's individual noise-doses range from 200% - 1,429%.

5.3.2 Scenario 2: Individual Noise-Dose in a Workday (90 dB-A Environment)

A hypothetical scenario of an 8 hour, 90 dB-A workday noise-exposure (i.e., 100% noise-dose, the permissible exposure limit) can be similarly modeled with and without TFOE adjustment (Figure 25 It is estimated that between 5 and 9 million U.S. workers are exposed to 8 hours duration of noise ranging from 85-90 dB-A (Caple, 1989); this is significant because workers are not required to wear hearing protection devices in these sound-levels (unless they have previously endured a standard threshold shift, or has not yet undergone baseline audiometry), though they would be required to be enrolled in a hearing conservation program. The described hypothetical workday scenario combination of 90 dB-A sound-level and 8 hours duration yields a 100% noise-dose - in other words, the OSHA permissible exposure limit. As in the concert scenario discussed above (pediatric+adolescent+adult groups), participants in this workday scenario (adult+adolescent groups) are each estimated to accumulate 100% noise-dose in this 8 hour 90 dB-A workday, based on sound-level meter or dosimeter measurement methods required by the regulations. However, if individual TFOE were again considered as part of an in-ear noise-dose calculation, the participant's estimated in-ear noise-doses would actually range from 200% (8 hours x 95 dB-A) to 1,053% (8 hours x 107 dB-A). Based on these estimated in-ear noise-dose data, the participant with the highest TFOE would accrue 5x the in-ear noise dose the participant with the lowest TFOE in this workday noise exposure.

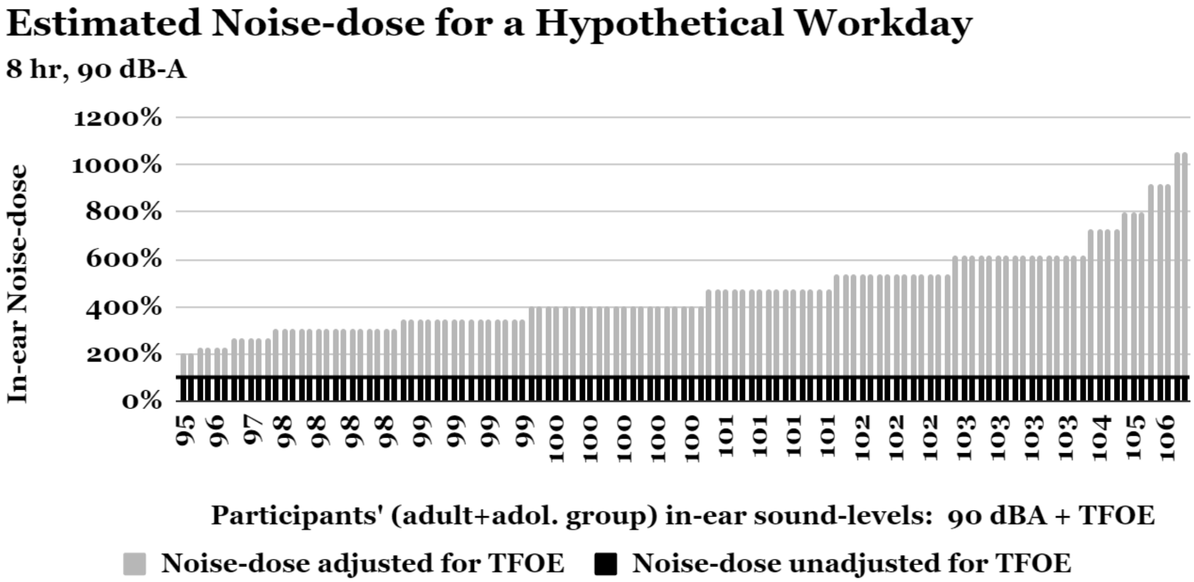

Figure 25.

In a hypothetical 8 hour workday exposure of 90 dB-A, participant's individual noise-doses are extrapolated with and without consideration of their individual TFOE. Without consideration of individual TFOE, each participant is estimated to accumulate 100% noise-dose for this workday, based on the sound-level measured outside the ear. With consideration of individual TFOE, participant's in-ear noise-doses are estimated to range from 200% - 1,053%.

5.3.3 Scenario 3: Individual Noise-Dose in a Workday (84 dB-A Environment)

The previous scenario illustrates in-ear noise-dose variation and subsequent NIHL-risk for the maximum (90 dBA TWA) noise-dose allowed in a workday environment that would not require hearing protection devices, though the participants would be required to enroll in a hearing conservation program and have an option of wearing HPDs (HPDs must be provided for exposures $\geq$85 dB-A time-weighted average, TWA). This next scenario (Figure 26) illustrates an 8 hour workday at 84 dB-A (i.e., 43% daily noise dose), which does not require workers to be enrolled in a hearing conservation program (sound-levels <85 dB-A). Yet, 95% of these participants would accumulate greater than 100% noise-dose for the workday, if dose was measured using their individual in-ear noise-dose. It is possible that those with the highest in-ear exposure levels will show changes in their hearing with continued exposure. If a worker was employed in this environment (84 dB-A for 8 hours per day) for multiple years before obtaining a baseline hearing test in preparation for a different, “dangerously noisy” job ($\geq$ 85 dB-A for 8 hours a day), their “baseline” hearing test could potentially reflect some hearing loss as a function of their cumulative exposure history in their previous “safe” job (in addition to sources of noise outside of work). Based on 29 CFR 1910.95, it is possible that some (or all) of this hearing loss would be attributed to non-occupational hearing damage (for additional discussion, see Dobie, 2015).

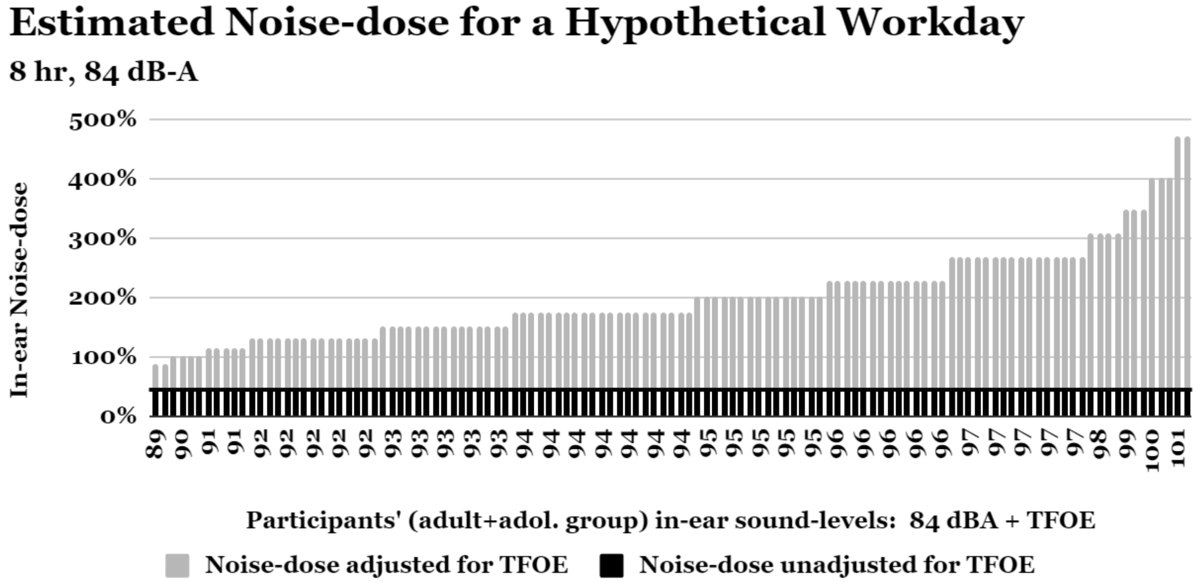

Figure 26.

An 8 hour workday exposure of 84 dB-A does not meet the 29 CRF 1910.95 criteria for placing a worker into a hearing conservation program. In a hypothetical 8 hour workday exposure of 84 dB-A, the participant's individual in-ear noise-doses are estimated with and without consideration of their individual TFOE. Without consideration of individual TFOE, each participant is estimated to accumulate 45% noise-dose for this workday. With consideration of individual TFOE, participant's in-ear noise-doses are estimated to range from 87% - 471%.

5.3.4 Scenario 4: Individual Noise-Dose in a Workday (78 dB-A Environment)

The current regulations that protect against NIHL are expected to result in 1 out of 4 workers incurring significant NIHL after a lifetime (40 year) career if they do not wear hearing protection, and are exposed to workplace noise at 90 dB-A for 8 hours per day. Illustrated below (Figure 27) is the in-ear noise dose assuring workplace exposures of 78 dB-A TWA. As shown in Figure 27, noise exposure at 78 dB-A TWA would bring in-ear noise-dose to 100% or less for 3/4 of worker and 200% or less for the top 25% of workers, assuming the current participant distribution accurately reflects TFOE distribution in workers.

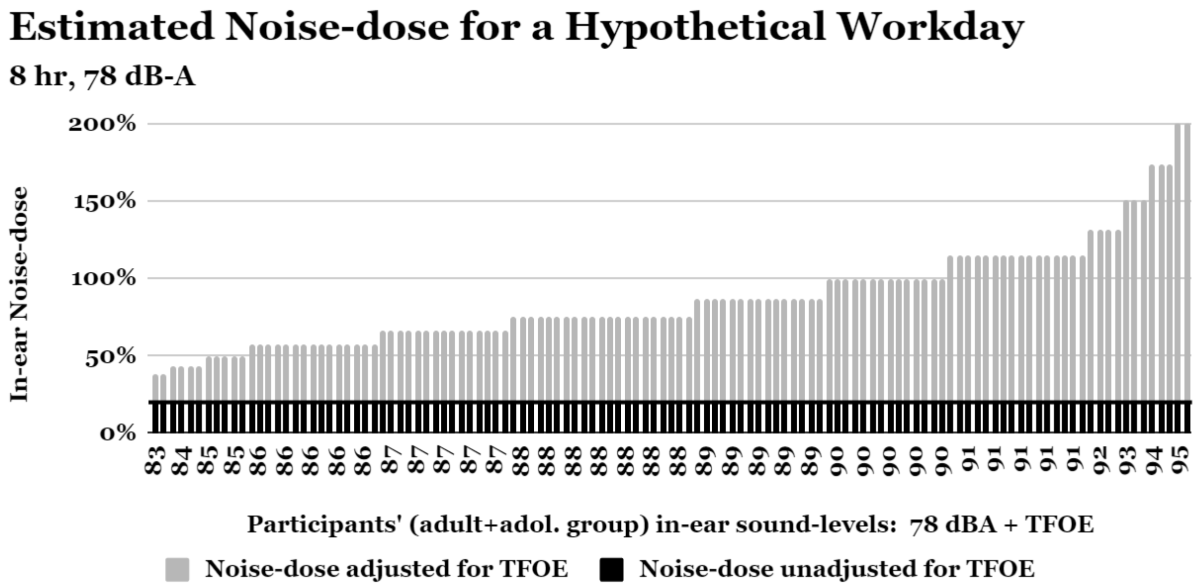

Figure 27.

In a hypothetical 8 hour workday exposure of 78 dB-A, the participant's individual noise-doses are extrapolated with and without consideration of their individual TFOE. Without consideration of individual TFOE, each participant is estimated to accumulate 20% noise-dose for this workday. With consideration of individual TFOE, participant's in-ear noise-doses are estimated to range from 38% - 200%, with only 1/4 of participants accruing in-ear noise-dose greater than 100%.

5.3.5 Scenario 5: Individual NIHL-dose in a Workday (73 dB-A)

The Environment Protection Agency (EPA) recommends a noise-exposure limit of 70 dB-A (average-level) for 24 hours to assure that no hearing loss whatsoever is incurred by even the most vulnerable individuals (EPA, 1974). Interestingly, the lowest sound-level that the participant's in this study could hypothetically endure in a workday without exceeding the PEL (Figure 28) amounts to 73 dB-A (average-level) for 8 hours.

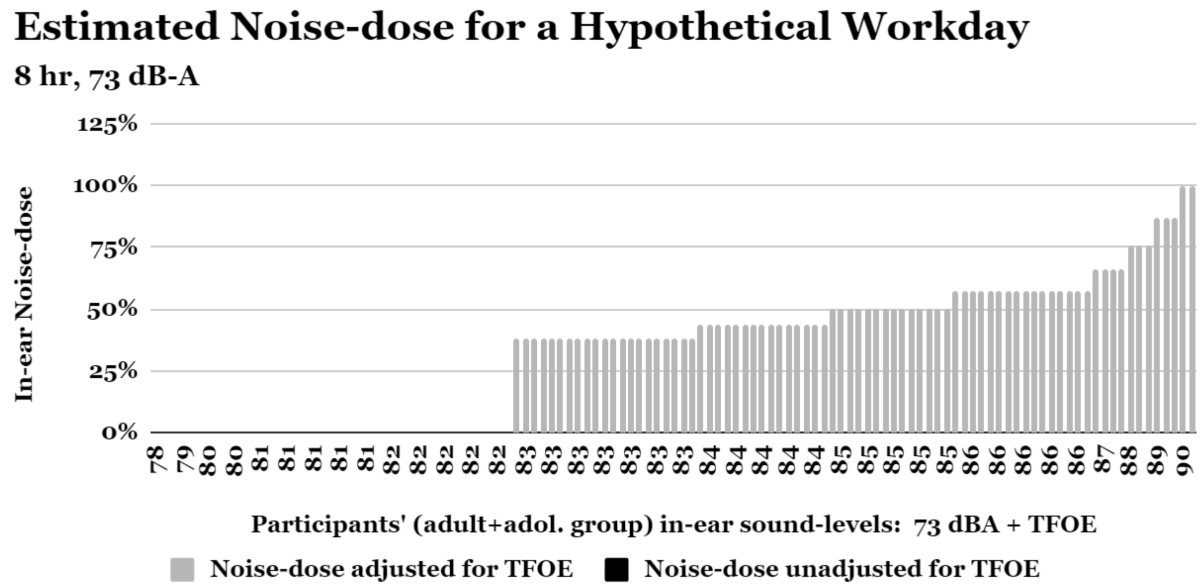

Figure 28.

In a hypothetical 8 hour workday exposure of 73 dB-A, participant's individual noise-doses are extrapolated with and without consideration of their individual TFOE. Without consideration of individual TFOE, each participant is estimated to accumulate 0% noise-dose for this workday. With consideration of individual TFOE, participant's noise-doses are estimated to range from 0% - 100%, with no participant's in-ear dose exceeding the OSHA PEL.

5.3.6 Scenario 6: Individual NIHL-Dose with 1 hour of Earbud-Listening

The above scenarios have related to free-field noise exposures; the next scenario discusses NIHL risk from an ear-level exposure, such as listening to music with earbuds. To illustrate the effect of TFEC on in-ear noise-dose, a hypothetical scenario of a 1 hour, 100 dB-A earbud-level sound exposure is discussed, which can be imagined as an hour-long earbud use during an exercise routine listening to music, or an hour-long bus or subway commute listening to music in background noise, or an hour-long video-game play using earbuds. This scenario can be modeled with and without TFEC adjustment (Figure 29) "Safe-listening duration" (y-axis) is shown for the 100 dB-A earbud-sound-level; i.e., the amount of time the participant could hypothetically listen to this sound-level before they reach the 100% OSHA PEL. Typically, the sound-level from an earbud is measured by removing the earbud from the participant's ear and placing it inside the silicone ear of a KEMAR sound-level meter manikin (designed to resemble the "average" adult ear), where it is measured by a microphone near the manikin's "eardrum". KEMAR's ear has a 5 dB TFOE (Berger et al., 2009), and so 5 dB is subtracted from the in-ear sound-level to obtain the free-field equivalent sound-level, and subsequently calculate a safe listening duration using the OSHA (or NIOSH) tables. In this case, a 100 dB-A sound-level inside KEMAR's ear would be treated as a 95 dB-A free-field equivalent, which may be safely listened to for 4 hours (black bars, using OSHA tables). However, if the free-field equivalent were calculated by subtracting the participant's true TFEC from the KEMAR sound-level measurement, safe-listening duration estimates would range from 6-28 hours (grey bars). As such, it seems that the KEMAR method of manikin measurement (i.e., applying the KEMAR TFOE to obtain the free-field equivalent) is likely to overestimate NIHL-risk.

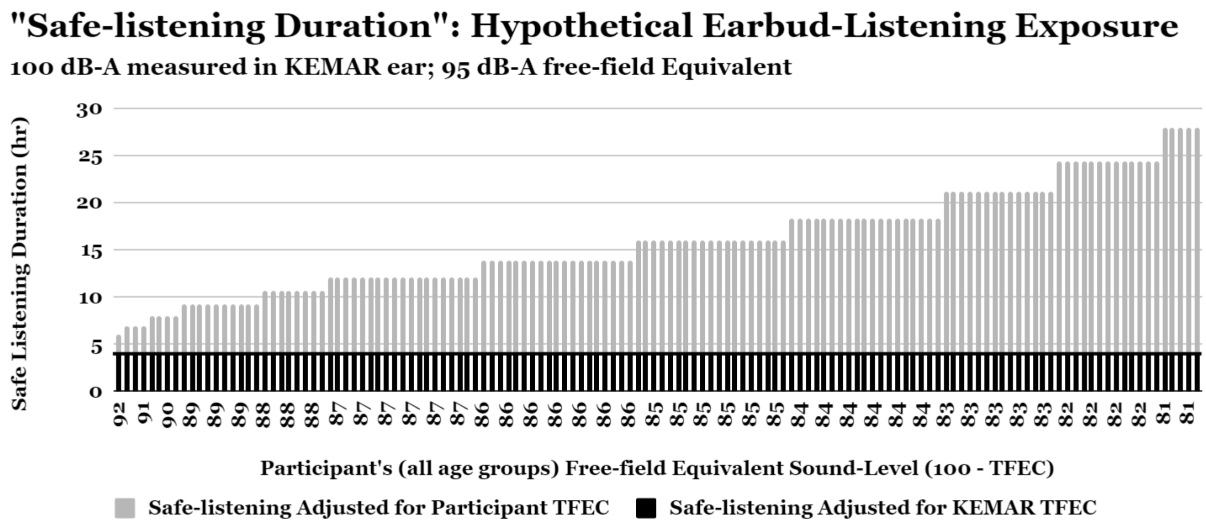

Figure 29.

Using a conventional KEMAR sound-level meter manikin (TFOE = 5 dB-A), the safe-listening duration of this earbud music listening noise exposure is estimated to be 4 hours, per OSHA tables. However, after accounting for participant's TFEC (TFEC 8-19 dB-A), safe-listening duration actually ranges from 6 - 28 hours.

5.3.7 Scenario 7: Loudness Discomfort Level Differences in Normal Hearing Listeners

Separate from the field of NIHL, there is a need to measure the loudest sound that a patient with hearing loss can tolerate. In hearing aid fittings, it is helpful to know the both lowest sound-level a patient can hear, and the highest sound-level a patient can tolerate, such that a hearing aid can be prescribed to fit amplified sounds into this range. Normal hearing listeners experience a loudness discomfort level (LDL) at 110 dB-SPL on average (range 100 - 120 dB). This LDL measurement is regarded as a "perceptual" measurement, which is why it is measured in "loudness". Loudness percept is of great concern when programming assistive auditory devices for patients with hearing loss, as they tend to experience not only increasing (worse) thresholds, but also decreasing (lower) LDLs; this decreased dynamic range is referred to as "recruitment".

Figure 30 illustrates that TFEC may be a mechanical factor that influences the patient's "perceptual" LDL; specifically, the sound-level present during the testing of the LDL may be physically higher in some ears, in parallel with self-reported LDL perception becoming uncomfortably loud. If we assume that participants with higher TFEC (i.e., more in-ear amplification of sound-levels during LDL testing) will report discomfort sooner (i.e., at lower sound-levels) during LDL testing, LDL variability in LDL in normal hearing listeners may have a mechanical explanation rather than a perceptual explanation. Additional research is necessary to assess the possibility that TFEC may be correlated with LDL.

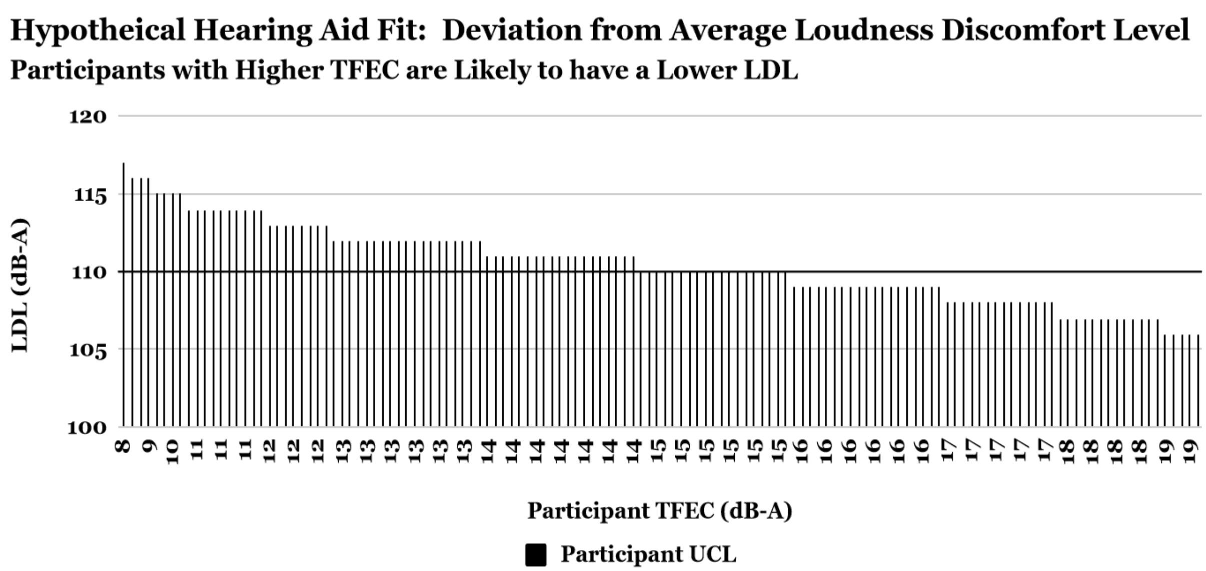

Figure 30.

The "average" LDL for a person with normal hearing is marked as 110 dB-A. Plotted are the participant's TFEC on the X-axis, and their anticipated LDL, if we assume TFEC to be correlated with LDL. In theory, an individual with higher TFEC would have a lower LDL.

5.4 NIHL Model Application

Although TFOE and TFEC measurements could improve the precision of individual noise-dose calculations and corresponding assumptions regarding vulnerability, these measurements are cumbersome in that professional equipment is required, and technical training and skills would be necessary to make these adjustments. As such, TFOE and TFEC measurements are unlikely to be feasible to implement in a noise-monitoring program that relies on certified occupational hearing conservationists, who do not currently receive training in these protocols. It is therefore worthwhile to consider the possibility of proxy metrics for TFOE and TFEC. Here, pinna height estimates 84% of TFOE within 3 dB-A. Because participants with higher TFOE values would (presumably) endure a more harmful noise-exposure (i.e., higher in-ear sound-level) than participants with the lower TFOE values, the ability to predict individual TFOE before exposure, using feasible measurements, would be a great advantage. Similarly, TFEC has reliable proxy metrics of earcanal volume (estimates 92% TFEC within 3 dB-A) and body height (estimates 88% TFEC within 3 dB-A). Body height is clearly the easier proxy metric, but portable tympanometric equipment is readily available, and training on the necessary otoscopic inspection and tympanometric probe selection and placement protocols (and, corresponding, infection control issues) is feasible.

5.4.1 Estimating High NIHL-risk

In order to use these models to identify individuals with “high” TFOE and TFEC, the user could draw the line anywhere they see fit for a low-risk group, average-risk group, and high-risk group. Perhaps the user will choose to be conservative and identify all individuals with “above average”

TFOE (>10 dB-A). Alternatively, the user could choose to be less conservative and identify only those individuals with “greater than 1 SD TFOE” (≥14 dB-A).

Again, it is up to the user of the model to decide which of the above criterion, or other criterion altogether, reflects their goals for a hearing conservation effort or program. Regardless of where the criterion is drawn, based on the 3 dB-A of variance in the TFOE estimate, model users should consider budgeting an “extra” 3 dB-A onto the TFOE estimate (created with the proxy metric). This 3 dB-A addition conservatively flags the most amount of individuals for possibly being at-risk for NIHL.

Of note, if the model’s user (i.e., tester) were to have the proper audiological training and equipment, there would be no need to estimate an individual's TFOE, as it could be precisely and directly measured following the methods in this dissertation. In this event, individuals with true TFOE values ≥ 14 dB-A (i.e., > 1 SD above the mean) could be flagged as “high-risk” (Figure 31). However, in using the model, if every estimated TFOE were adjusted for our “worst case scenario +3-dB variance” mentality, 100% of true TFOEs ≥ 14 dB-A could be flagged if the line for “at-risk” TFOE estimations was drawn at 13 dB-A (Figure 31). This is a significant improvement from the current model, which identifies 0% of individual vulnerability. By the same token, of the participants that do not truly meet high-risk criteria – but are flagged as such nonetheless (i.e., false positives) - 17% of them fall above the mean TFOE (> 10 dB-A). Therefore, on a positive note, although these subset of participants are technically false-positives for high-risk criteria, they are - in fact - at some amount of increased risk, because their TFOE is greater than the mean TFOE.

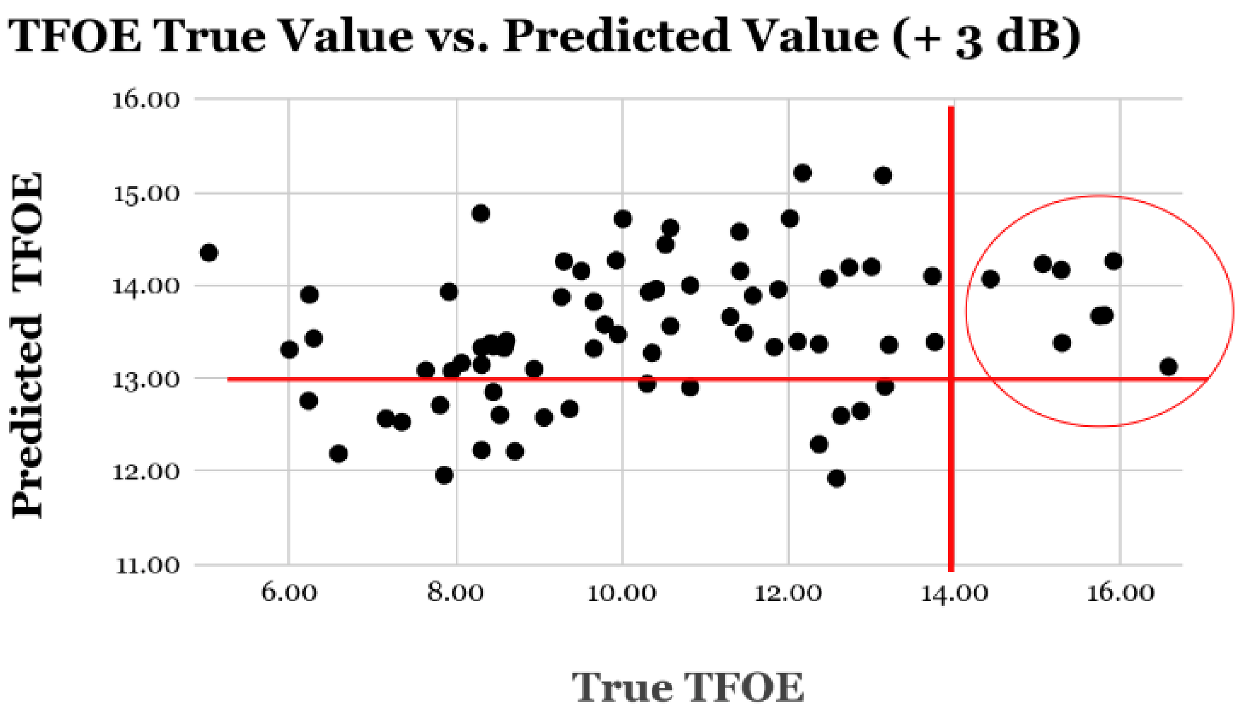

Figure 31.

The participants in the red circle have a true TFOE $\geq$ 14 dB-A (i.e., > 1 SD from the mean), and meet the high-risk criterion. Using the model and assuming the "worst-case scenario" mentality (+3 dB-A variance adjustment to the TFOE estimation, i.e., worrying that the participant's TFOE is actually 3 dB higher than the estimation), 100% of high-risk individuals would be flagged (i.e., true positives). Of the individuals with TFOE < 14 dB-A identified as high-risk (i.e., false positives), many do have TFOEs that are – in fact – above the mean TFOE (10 dB-A), and are therefore at some degree of increased risk, compared to average risk
.

5.4.2 Improving Clinical Trial Design for Otoprotective Agents

A final application of this study's TFOE and TFEC data is the potential for improvement upon clinical trial design within studies of otoprotective agents if individual TTS variability can be reduced based on delivery of a calibrated in-ear sound exposure level. Le Prell et al. (2012), for example, developed a model using a highly controlled music-exposure administered via insert-earbuds. Although all participants theoretically receive the same noise-dose, significant variability was observed not only in pilot studies (Le Prell et al., 2012) but also in two completed clinical trials assessing a dietary supplement (Le Prell, Fulbright et al., 2016) and a pharmaceutical intervention (Kil et al., 2017). Within control cohorts, some participants had no change in thresholds after music-exposure, whereas others had as much as 20 dB-HL threshold shifts immediately following the noise-exposure. With regards to these previous studies assessing noise-induced threshold shift and its prevention, it is reasonable to speculate that the degree of variability in TTS measurements may have been, at least in part, a consequence of differences in the in-ear exposure sound-level and individual in-ear dose. Differences in individual NIHL vulnerability are well-known across the literature, and have the potential to impact variability across participants in clinical trial designs (for review and discussion of different clinical trial designs, see (Le Prell and Lobarinas, 2015; Lynch et al., 2016).

5.5 Conclusions and Future Directions

The individual transfer function of the open ear (TFOE) was observed to be highly variable across individuals (5 - 19 dB-A); the effect of this variability on in-ear noise-dose provides additional support for suggestions that TFOE (or proxy metrics of TFOE) should be used to improve the precision of NIHL risk assessment. The principal investigator proposes that TFOE has the potential to substantially explain why individuals exposed to the same noise insult can develop significantly different amounts of temporary and permanent hearing threshold shift.

With these data in hand, it is possible to imagine including individual TFOE as a factor for identifying individuals with high in-ear noise-dose and subsequently high NIHL-risk estimation. The finding that pinna height measurements (highly feasible, non-invasive, and non-technical) were reliably associated with TFOE suggests that pinna height could be a simple proxy metric to be utilized when direct TFOE measurements are not feasible.

The individual transfer function of the ear canal (TFEC) was observed to be highly variable across individuals (8 - 19 dB-A). The effect of this variability on in-ear sound exposure provides support that TFEC should be used to improve the precision of individual NIHL risk assessment in ear-level exposures, such as earbud use. The data suggest that TFEC has the potential to substantially explain why individuals exposed to the same ear-level noise insult can develop significantly different amounts of temporary and permanent hearing threshold shift. With these data in hand, is possible to imagine including individual TFEC as a factor for identifying individuals at high-risk for high in-ear noise-doses and subsequently high NIHL-risk estimation. The finding that earcanal volume and body height measurements (highly feasible, non-invasive, and non-technical) were reliably associated with TFEC measurements suggest that these could be simple proxy metrics to be used when TFEC cannot be measured directly.

In conclusion, individual variability in TFOE and TFEC could - at least in part - explain why individuals show considerably different NIHL when exposed to the same noise-insult. The observed TFOE and TFEC measurements ranged from 5-19 dB-A; that TFOE and TFEC could influence individual susceptibility to NIHL is especially convincing given that NIHL risk doubles with every 3-5 dB-A sound-level increase (for detailed discussion, see Dobie & Clark 2014, Dobie & Clark, 2015). Follow-up investigation is needed to determine the relationship between TFOE and TFEC and audiometric threshold / otoacoustic emission amplitude shift following a noise-insult, in order to confirm external-ear amplification as a source of variability in vulnerability to NIHL across individuals.

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BIOGRAPHICAL SKETCH

Sarah Grinn was raised in Okemos, Michigan and attended Michigan State University, where she earned a BA in communication sciences and disorders and a double major in Spanish. Alongside her early academic endeavors, Sarah was also a varsity athlete on the Michigan State women's water polo team. After finishing her undergraduate degree, she moved to Gainesville, FL to attend The University of Florida, where she earned her AuD and took up a specific interest in hearing conservation. Sarah completed her audiology residency in Dallas, TX at The University of Texas at Dallas, where she subsequently earned a PhD studying noise-induced hearing loss under the mentorship of Dr. Colleen Le Prell. Upon her PhD graduation, Sarah accepted a position as an assistant professor at Central Michigan University to continue her program of research. Sarah spends her free time on the water or on the slopes in northern Michigan.

CURRICULUM VITAE

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Education

1. The University of Texas at Dallas — 2017 – present
   PhD Candidate Comm. Sciences and Disorders
2. The University of Florida — 2013 – 2017
   AuD Audiology
3. Michigan State University — 2009 – 2013
   BA Comm. Sciences and Disorders
   Dual major Spanish Language

Clinical License and Certificate

1. Texas State Licensed Audiologist — 2017 – present
2. ASHA Certificate of Clinical Competence — 2018 – present

Grant Funding (Principal Investigator)

1. 2018 American Academy of Audiology New Investigator Grant
   "Effects of Firearm Noise Exposure on Cochlear Nerve Response Amplitude"
2. 2018 Texas Speech-Language Hearing Foundation Research Grant
   "Individual Noise-dose Variability and NIHL Risk: Modeled with Open Ear Transfer Function in Children"
3. 2017 National Hearing Conservation Student Research Grant
   "Effects of Firearm Noise Exposure on Cochlear Nerve Response Amplitude"
4. 2017 Susan and Jim Jerger Research in Audiology Fellowship
   "Individual Noise-dose Variability and NIHL Risk: Modeled with Open Ear Transfer Function in Adults"

Grants in Preparation (Principal Investigator)

1. NIH R21 Exploratory Research Grant
   "Individual Noise-Induced Hearing Loss Risk Relative to Individual Transfer Function of the Open Ear"

Grant Support (Research Assistant)

1. Department of Defense Grant - Walter Reed National Military Medical Center / Subcontract UT Dallas Advanced Hearing Research Center
   "Functional Impairment in Service Members with Normal Audiometric Thresholds"

Peer-Reviewed Publications

1. **Grinn S.K,** Wiseman K.B, Baker J.A, Le Prell C.G. (2017). Hidden Hearing Loss? No Effect of Common Recreational Noise Exposure on Cochlear Nerve Response Amplitude. *Frontiers in Neuroscience, 11:465. doi: 10.3389/fnins.2017.00465*

Manuscripts Under Review or In Preparation

1. **Grinn, S.**, Palmer, K., Le Prell, C.G. Smartphone Apps Accurate within 2-dB of Gold Standard at High Intensities.
2. **Grinn, S.,** Brooke, K., Crosson, S. Le Prell, C.G. Accuracy of Top-Rated Sound Level Meter Smartphone Apps for iPhone.
3. **Grinn S.,** Le Prell C.G. In-ear Sound Level Measurement Methods: A Comparison of Clinical and Laboratory Gold Standards and Implications for Earbud Music-Induced Hearing Loss.
4. **Grinn S.**, Le Prell C.G. Earcanal Resonance: Implications for Individual Susceptibility to Noise-Induced Hearing Loss.
5. **Grinn, S.,** Iola, A. Le Prell, C.G. Relationship Between Transfer Function of the Open Ear and Peak-Resonance of the Occluded Earcanal.
6. **Grinn, S.**, Gittleman, S., Le Prell C.G. Earcanal Resonance and Speech-In-Noise Performance.
7. Zaccardi, T., **Grinn, S.**, Le Prell C.G. Attenuation of High Fidelity Hearing Protection Devices.
8. **Grinn S.,** Le Prell C.G. Effects of Firearm Use on Cochlear Nerve Response Amplitude.

Awards

1. UT Dallas - PhD Student Research Presentation Travel Award 2018
   2018 World Congress of Audiology (Cape Town, South Africa)
2. UT Dallas - PhD Student Research Presentation Travel Award 2017
   2018 American Academy of Audiology (Nashville, TN)
3. ASHA Audiology and Hearing Science Research Travel Award (ARTA) 2017
   2017 ASHA Convention (Los Angeles, CA)
4. Future Leaders in Audiology Student Conference (FLASC) Award 2017
   The FLASC conference prepares identifiable student leaders to contribute to the state and national legislation that shapes our scope of practice and gold-standards of evidence-based clinical care.
5. Todd H. Porter Student Poster Award 2016
   Awarded on the topic of cochlear synaptopathy ("hidden hearing loss"), presented at Texas Academy of Audiology Annual Conference.

Invited Speaker

1. Conference Presenter - American Academy of Audiology 2020. New Orleans, LA. “Effects of Firearm Exposure on Cochlear Nerve Response Amplitude in Humans” 2020
2. Conference Presenter - National Hearing Conservation Association 2020. Location TBA. “Effects of Firearm Exposure on Cochlear Nerve Response Amplitude in Humans” 2020
3. Guest Lecture - The University of Florida - AuD Distance Learning Program. “Noise-Induced Hearing Loss in the Workplace: Handicap and Allocation”. 2019
4. Guest Lecture - The University of North Texas. “My Audiology Practice Prescribes, Fits, and Verifies Hearing Protection Devices”. 2019
5. Conference Presenter - Texas Academy of Audiology 2018. The Woodlands, TX. “What are you Doing about Pediatric Noise Exposure?”. 2018
6. Guest Lecture - The University of Texas at Dallas AuD Program. “Anatomy and Physiology of Audition”. 2018
7. Guest Lecture - The University of Florida - AuD Distance Learning Program. “Noise Control Overview and Federal Regulations”. 2017
8. Guest Lecture - Zero Harm Global Safety Week - CHEP Equipment Pooling Systems. “Hearing Conservation Programs, Hearing Protection Devices, and Noise Regulations” 2017

Research Presentations

1. Iola, **Grinn,** Le Prell. Relationship between Peak Resonance & Transfer Functions of the Open Ear.. *Poster presentation, National Hearing Conservation Association 2019. Grapevine, TX.*
2. Gittleman, **Grinn,** Le Prell. Relationship Between External-ear Gain in the Speech Frequencies and Self-reported Difficulty Understanding Speech in Noise. *Poster presentation, National Hearing Conservation Association 2019. Grapevine, TX.*
3. **Grinn**. Noise-Dose and Risk Variability Demonstrated with Inside-Ear Probe Microphone Measurements. *Podium presentation, 34th World Congress of Audiology 2018. Cape Town, South Africa.*
4. **Grinn,** Le Prell. Using Real-Ear Measures to Model Individual Risk for Noise-Induced Hearing Loss. *Poster presentation, American Academy of Audiology 2018. Nashville, TN.*
5. **Grinn,** Jackson**.** Expanding Clinical Services: The Other Patient in the Room - How to Fit, Verify, and Dispense Hearing Protection Devices to Patients and Caregivers. *Podium presentation, American Academy of Audiology 2018. Nashville, TN.*
6. Zaccardi, Palmer, **Grinn,** Le Prell. Attenuation Using High Fidelity Hearing Protection Devices. *Poster presentation, National Hearing Conservation Association 2018. Orlando, FL.*

7. Palmer, Zaccardi, **Grinn,** Le Prell. Accuracy of "NIOSH SLM" and "Sound Level Meter" Apps for iPhone. *Poster presentation, National Hearing Conservation Association 2018. Orlando, FL.*
8. **Grinn,** Baker, Wiseman, Le Prell. Hidden Hearing Loss: ABR Wave I Amplitude Before and After Noise Exposure. *Poster presentation, American Academy of Audiology 2017. Indianapolis, IN.*
9. Baker, **Grinn,** Wiseman, Le Prell. Changes in Performance on Speech Tests in Quiet and Noise after Recreational Noise Exposure. *Poster presentation, American Academy of Audiology 2017. Indianapolis, IN.*
10. Wiseman, Baker, **Grinn**, Le Prell. Relationship between DPOAE Amplitude and Recreational Noise Exposure. *Poster presentation, American Academy of Audiology 2017. Indianapolis, IN.*
11. **Grinn**, Palmer, Zaccardi, Le Prell. Sound Level Meter Apps for iPhone: Accuracy of "SPL Graph" and "SPL Meter". *Poster presentation, National Hearing Conservation Association 2017. San Antonio, TX.*
12. **Grinn**, Lobarinas, Le Prell. Sound Level Accuracy of Jolene Device and Verifit Relative to KEMAR Laboratory Gold Standard. *Podium presentation, National Hearing Conservation Association 2017. San Antonio, TX.*
13. **Grinn,** Baker, Wiseman, Le Prell. Hidden Hearing Loss: ABR Wave I Amplitude Before and After Noise Exposure. *Poster presentation, National Hearing Conservation Association 2017. San Antonio, TX.*
14. Baker, **Grinn**, Wiseman, Le Prell. Changes in Performance on Speech Tests in Quiet and Noise after Recreational Noise Exposure. *Poster presentation, National Hearing Conservation Association 2017. San Antonio, TX.*
15. Wiseman, Baker, **Grinn**, Le Prell. Relationship between DPOAE Amplitude and Recreational Noise Exposure. *Poster presentation, National Hearing Conservation Association 2017. San Antonio, TX.*
16. **Grinn**, Baker, Wiseman, Le Prell. ABR Wave I Amplitude Before and After Noise Exposure. *Poster presentation, Texas Academy of Audiology 2016 Conference. Frisco, TX.*
17. Baker, **Grinn,** Wiseman, Le Prell. Changes in Performance on Speech Tests in Quiet and in Noise after Recreational Noise Exposure. *Poster presentation, Texas Academy of Audiology 2016. Frisco, TX.*
18. **Grinn**, Brooke, Crosson, Lobarinas, Le Prell. Accuracy of iPhone Sound Level Meter Apps. *Poster presentation, National Hearing Conservation Association 2016. San Diego, CA.*
19. **Grinn**, Brooke, Crosson, Lobarinas, Le Prell. Accuracy of iPhone Sound Level Meter Apps. *Poster presentation, UF 2015 Graduate Student Research Day. Gainesville, FL.*

Research Positions Held

1. Lab Manager, PhD Candidate – UT Dallas Hearing Conservation Laboratory — May 2016 – present

   PhD PI projects: 1. Effects of recreational noise exposure on cochle nerve response amplitude (co-PI); 2. Effects of firearm noise exposu on cochlear nerve response amplitude; 3. Individual noise-dose variability and NIHL risk modeled with open ear transfer function; Accuracy of sound level meter smartphone apps; 5. Sound level accuracy of a "Jolene" SLM manikin relative to the KEMAR laboratory standard; 6. Speech-in-noise performance relative to earcanal resonance.
2. PhD Research Assistant – Department of Defense Grant - Walter Reed National Military Medical Center / Subcontract UT Dallas Advanced Hearing Research Center — Oct. 2018 – present

   "Functional Impairment in Service Members With Normal Audiometric Thresholds". Our subcontracted site performs comprehensive peripheral and central audiological testing to obtain normative data from a normal-hearing population, against which the parent site compares etiology and implications of blast-related auditory damage in the Active Duty military population.
3. AuD Research Assistant – UF Hearing Research Center — Apr. 2015 – June 2015

   Collected audiometric data from human participants testing the preventative effects of a vitamin supplement on temporary threshold shift induced by 4 hr 100 dBA in-ear music exposure (supervised by Colleen Le Prell, PhD)
4. Undergraduate Research Assistant – MSU CSD Department — May 2012 – May 2013

   Assisted in initial laboratory setup and recruitment of human participants for a study exploring the effects of age and hearing loss on spectral integration and speech identification (supervised by Mini Shrivastav, PhD)

Languages

1. English – native fluency
2. Spanish – professional fluency

Professional Memberships

1. Student Academy of Audiology — 2013 – present
2. National Hearing Conservation Association — 2015 – present
3. Texas Academy of Audiology — 2016 – present
4. Texas Speech and Hearing Association — 2017 – present
5. American Speech Language and Hearing Association — 2018 – present

Service

1. Conference Abstract Reviewer – National Hearing Conservation Association 2019
   Reviewed research and industry presentation submissions to the 2019 NHCA annual conference in Grapevine, TX.
2. Conference Program Committee Member – National Hearing Conservation Association 2018
   Coordinated conference schedules, events, presentations, and social activities of the 2018 NHCA annual conference in Orlando, FL.
3. Student Delegate – National Hearing Conservation Association 2016, 2017
   Appointed by the NHCA President to represent student interests at all Executive Council meetings and at the annual conference (San Antonio, 2017, Orlando, 2018); grew student membership by more than 100% with strategic recruitment.
4. Student Coordinator, UT Dallas Cochlear Implant Summer Listening Camp 2016
   Organized events designed to enhance listening skills, and documented individual auditory improvement in pediatric cochlear implant users (Dallas, TX).
5. Student Liaison to Faculty, UF Student Academy of Audiology 2015, 2016
   Elected Board Member of the UF Student Academy of Audiology. Collaborated with faculty to review and improve the UF AuD program's clinical preparation model and academic foundation (Gainesville, Florida).
6. Committee Member, University of Florida Project Yucatan 2014, 2016
   Student clinician and Spanish interpreter for a humanitarian trip providing audiologic evaluation and rehabilitation services in Merida, Mexico and the greater Yucatan area (Merida, MX).
7. Committee Member, University of Florida Little Ears Field Day 2015, 2016
   Organized a charitable field-day event for children with hearing loss to raise funds for local educational audiology programs (Gainesville, FL).
8. Student Clinician, Special Olympics 2016
   Provided hearing screening services for competing athletes and promoted community awareness of the causes and effects of hearing loss (Orlando, FL).
9. Appointed Judge, American National Championship Forensics Tournament 2016
   Evaluated and ranked collegiate speech and debate teams in public speaking categories such as informative speaking, persuasive speaking, and impromptu speaking in an annual, national-level competition (University of Florida).

10. Appointed Judge, Florida Invitational Forensics Tournament — 2015, 2016

Evaluated and ranked collegiate speech and debate teams in public speaking categories such as informative speaking, persuasive speaking, and prose interpretation in an annual, regional-level competition (University of Florida).

11. Student Interpreter, Michigan State University Angel Notion Clinic — 2012

Spanish interpreter for a humanitarian trip organized by medical and speech language pathology students and faculty to provide speech and language rehabilitative services free of cost; interpreted negotiation of clinic expansion (Merida, MX).

Teaching Positions Held

1. Graduate Teaching Assistant – UT Dallas Audiology Department — Aug. 2018 – Dec. 2018

   Independently built and instructed the weekly lab, “Evaluation and Fitting of Amplification Systems” for AuD students (mentored by Edward Lobariñas, PhD)
2. Graduate Teaching Assistant – UT Dallas Audiology Department — Jan. 2018 – May 2018

   Assisted “Introduction to Audiology” for undergraduate CSD students; aided course organization, grading, and independently conducted several guest lectures (mentored by Jeffrey Martin, PhD).
3. Graduate Teaching Assistant – UT Dallas Audiology Department — Aug. 2017 – Dec. 2017

   Independently built and instructed the weekly lab, “Evaluation and Fitting of Amplification Systems” for AuD students (mentored by Edward Lobariñas, PhD)
4. Graduate Teaching Assistant – UF Oral and Written Communication Department — Aug. 2013 – May 2016

   Primary and sole instructor of the undergraduate course, “Public Speaking” for 8 consecutive semesters; independently built and instructed all syllabi, lectures, assignments, and grading (mentored by Stephanie Webster, PhD)
5. Undergraduate Teaching Assistant – MSU CSD Department — May 2012 – June 2012

   Assisted graduate-level speech-pathology course, “Dysphagia”; course organization, grading, and ASHA CEU documentation (mentored by John Rosenbek, PhD)

Clinical Addendum

Clinical Positions

1. Audiology Resident – UT Dallas Callier Center for Communication Disorders — May 2016 – May 2017

   Well-rounded university clinical practicum in diagnosis and rehabilitation of persons with auditory and vestibular dysfunction; focus in pediatric cochlear implants and diagnostic electrophysiology (supervised by Shawna Jackson, AuD, CCC-A)

2. Graduate Student Audiology Clinician – UF Health & Shands Hospital — Aug. 2013 – May 2016

   Well-rounded, large hospital practicum in diagnosis and rehabilitation of persons with auditory and vestibular dysfunction; focus in pediatric and adult cochlear implants and hearing loss diagnostics (supervised by Emily McClain, AuD, CCC-A)

Practicum Locations

- UT Dallas Callier Center for Communication Disorders – Dallas, TX
- UT Dallas Callier Center for Communication Disorders – Richardson, TX
- Dallas Independent School District
- Shands Hospital Mother/Baby and NICU Units
- Shands Hospital Craniofacial Center
- Shands Hospital ENT and Allergy at Hampton Oaks Medical Center
- UF Health Speech and Hearing Center
- UF Health Park Avenue Speech and Hearing University Center
- UF Health Oak Hammock Rehabilitation and Medical Services

Clinical Skills

- ENT audiometric eval., adult and pediatric
- ENT audiometric eval., craniofacial clinic
- ABR/ASSR, resting and sedated
- VNG/CDP/caloric assessment
- VEMP assessment
- EcochG assessment
- Acoustic reflex assessment
- Otoacoustic emission assessment
- Newborn hearing screening
- Cochlear implant eval. and mapping
- Hybrid cochlear implant eval. and mapping
- Tinnitus eval., counseling, and rehabilitation
- Aural rehab; “Living with Hearing Loss”
- Digital hearing aid programming
- Osseointegrated hearing aid programming
- Auditory processing disorder assessment
- FM/DM technology programming
- Cerumen management
- Educational audiology program assistance
- Occupational noise exposure monitoring
- Ototoxic medication monitoring